Chapter 1:
Introduction

1.1 *Thesis Introduction*

A prosthesis is an artificial device that replaces a part of the human body which is absent due to illness, injury or deformity. The design and construction of any prosthesis depends both on the complexity of the body part being replaced and the rehabilitative requirements of the prosthesis user.

Upper limb prostheses are prescribed for those individuals who have either partial or complete upper limb absence, which may either be acquired (through amputation) or congenital (absent at birth). They are fitted by healthcare professionals called Prosthetists, who work as part of a multi-professional rehabilitation team, usually within dedicated disablement service centres within the United Kingdom. Upper limb prostheses should primarily be comfortable to wear, functionally useful and aesthetically compatible with the requisite body parts. Comfort is achieved through an intimately matched prosthetic interface, called a socket, which directly encloses the remains of the most distal arm segment, or residual limb. The socket attaches to other components within the prosthesis, which normally include a hand or other terminal device or active prehensor (grasping device) (1).

There are three types of upper limb prostheses that are commonly available for potential prosthesis users; myoelectric prostheses, body-powered prostheses and cosmetic prostheses (2). Myoelectric prostheses are controlled by electro-myo-graphic (EMG, or myoelectric) signals generated from skeletal muscles within the remaining distal segment of the arm, known as the residual limb. The myoelectric signals are acquired by surface electrodes that are housed within the walls of the prosthetic interface, (known as the socket), which fits over the residual limb. Matching the socket shape and size with the residual limb shape and volume is essential for effective prosthesis fitting (3).

Myoelectric prostheses are relatively complex advanced upper limb prostheses and have received relatively high levels of exposure within the media, where they are often anecdotally termed ‘bionic prostheses’. Body-powered prostheses and cosmetic prostheses are usually much less complex, and far less expensive than myoelectric prostheses.

Body-powered prostheses are purely functional, cosmetically poor and have changed little since their inception over a century ago (4, 5). They require an external harness, which uses specific body movements to actively control joint segments and prehensile (grasp) function. They are still widely regarded as the most functional upper limb prosthesis type (6). By contrast, cosmetic prostheses are primarily aesthetic, but can also be used for simple daily tasks, such as holding or steadying objects, even though they have no active prehensile capability (6, 7).

Myoelectric prostheses combine aspects of both cosmetic and body-powered prostheses, incorporating electrically-powered active prehension and a relatively cosmetic appearance. In contrast to body-powered prostheses, myoelectric prostheses have the significant advantage of requiring no external harness for prosthesis control, and have also undergone significant improvements to their technical specifications during the last 30 years. The development of next-generation multifunctional hands with numerous degrees of freedom (8) combined with control system improvements such as myoelectric signal pattern recognition (9, 10) has greatly increased the potential capability of myoelectric prostheses. However, evidence suggests that these improvements are not being matched by a proportional increase in prosthesis user satisfaction (5, 11, 12) and usage rates (13-21); suggesting that other elements may be restricting prosthesis functionality.

One prosthetic element that has received relatively little attention over recent years within upper limb prostheses is the prosthetic socket, despite the fact that it is generally regarded as crucial to prosthesis usage (22–25). The upper limb prosthesis socket is a rigid, usually laminated, plastic shell (**figure 1.1a**), which normally completely encloses the residual limb. The role of the Prosthetist is primarily concerned with providing a well-fitting socket for the prosthesis user (1).

The socket has a number of functions (please see **chapter 2**, section 2.6) but primarily it should provide a secure, comfortable environment for the residual limb, and also act as an attachment point for other components, such as the forearm section in below elbow (transradial) prostheses (22-25). In myoelectric prostheses, the socket also has an important control function, as it houses the electrodes necessary for prosthesis operation. However, the majority of myoelectric sockets vary little from those employed in other prosthesis types (24,

25), and still rely on principles developed and implemented before the requirements of clinical myoelectric control systems were fully recognised and understood (26-29).

Figure 1.1: Electrodes fixed into rigid socket (A); Impression on skin from electrode contact (B) (30)

One particular problem that can affect myoelectric control is relative movement between the electrode and the surface of the skin. Where surface electrodes are used in other applications, for example in the measurement of heart rhythm, they are adhered to the skin's surface (31). However, in myoelectric sockets, attachment of the electrodes to the skin in addition to the socket is not possible because the user will need to don and doff their prosthesis. For this reason, the electrodes are located within fixed housings which are integrated within the prosthetic socket wall (**figure 1.1**). Consequently, this means that any movements, which occur between the socket and the skin, may also occur between the electrode and the skin.

Movement between the socket and the residual limb in most types of prosthesis is well documented, although this is experienced more frequently in lower limb prostheses (32). Upper limb prostheses do not experience the effects of large ground reaction forces during usage, nor the relatively large weight-bearing loads imparted during walking which lower limb prostheses experience. However, they do need to provide a much wider range of functional uses with significant ranges of movement during normal usage. Commonly employed activities have been categorised as the 'Activities of Daily Living' (ADLs). The prosthesis user's ability to undertake ADLs provides useful information regarding the capabilities of upper limb prostheses. Consequently, ADLs will be used within this thesis

with respect to prosthesis assessment and functionality, and are described in more detail within **chapter 2**.

The loads imparted at the interface between the socket and the skin in myoelectric upper limb prostheses and the subsequent relative movement may vary, but little is known regarding how much movement occurs and whether this is large enough to affect and alter electrode-to-skin contact.

Systems such as roll-on sockets have been devised to minimise the effects of these movements (33-35), but they are not frequently used in upper limb prostheses and have other disadvantages, which will be examined later in the thesis. The normal socket types used in myoelectric prostheses incorporate methods of socket suspension, fitting and attachment that are inherently similar to most types of prostheses currently available, and can in theory allow such movements to occur (28, 36, 37).

In body-powered and cosmetic prostheses, socket movement with respect to the skin will have little effect on prosthesis capability as they play no part in the prosthesis control processes. However, in myoelectric prostheses, the electrodes used to acquire the myoelectric signals require secure contact with the skin at all times for optimum function (38-40). Movement between the electrode and the surface of the residual limb could lead to the production of motion artifacts, or 'false' myoelectric signals, which may interfere with prosthesis control (38-40). Although the socket is rigid, the residual limb is fleshy and inherently mobile. This means that movement between the skin's surface and the socket wall, and hence the electrode, is distinctly possible (41, 42). Although the resultant effects on signal acquisition are widely acknowledged (9, 10, 39, 40), and clinical anecdotal evidence regarding the problems with myoelectric prosthesis control are widespread, little documented evidence exists regarding the extent of the effect of these movements on prosthesis functionality.

In addition, once the electrode is secured within the socket wall, little if any adjustment or alteration to its contact security with respect to the surface of the skin or alignment with respect to the muscle fibres producing the myoelectric signal, is possible. The correct placement of the electrode within the socket, and its relative alignment and contact security with respect to the skin, is reliant upon the skill and experience of the Prosthetist.

The skills base of the Prosthetist has changed significantly in recent decades; the reasons behind these changes, and their potential consequences with regard to the area of the thesis, are highlighted and discussed within **Appendix E-** *The changing education of Prosthetists*.

Anecdotal evidence suggests that some Prosthetists will use elastic bands, secured around the external surface of the electrode, to try to restrict electrode movement or electrode detachment from the skin's surface. Anecdotal evidence also suggests that felt washers or plastic inserts may also be used between the inner and outer socket (if an outer socket is used) to increase contact security between the electrode and the skin. However, both of these aforementioned methods are relatively crude and inaccurate.

The need for more evidence as to what effect immobile electrodes (which are fixed and contained within upper limb prosthetic sockets in simple housings) have on myoelectric prosthesis functionality prompted the development of this thesis. The evidenced high rates of rejection of myoelectric prostheses by upper limb amputees, linked to lack of prosthesis functionality, suggested that changes in design to electrode housing mechanisms and development of new novel designs could significantly reduce prehensile disruption, thereby improving prosthesis functionality and user uptake.

More research is also needed to confirm the extent to which surface electrodes fixed within myoelectric prosthetic sockets allow motion artefacts to occur during typical ADLs, thereby disrupting prehensile prosthesis control and resulting in restricted prosthesis functionality. In addition, the mechanisms and solutions to this phenomenon needed to be investigated in order to provide enhanced functionality for upper limb myoelectric prosthesis users.

1.2 *Thesis overview*

To meet the requirements outlined previously, the following investigations were undertaken:

1. A prosthesis user analysis, via a targeted questionnaire, identifying existing links or problems with socket fit, electrode contact and prosthesis response in myoelectric upper limb prostheses.

2. An investigation contrasting current best practice in the field of myoelectric signal acquisition with current clinical practice employed within myoelectric prostheses.
3. The development of potential improvements to signal acquisition within current types of prosthetic socket by means of a novel electrode housing device.
4. An analysis comparing common upper limb movements and activities with their potential effect on signal acquisition.

Firstly, evidence needed to be gathered from current myoelectric prosthesis users highlighting any difficulties with prosthesis control due to variations in their perceived electrode to skin contact security and socket tightness. These would need to be linked to their ability to perform ADLs, since these represent the movements, and the subsequent control interruptions, most likely to be employed and encountered by amputees. Variations in prosthesis loading, the effects of carrying, lifting and pulling, and the effect of different movements on specific electrode contacts, were also investigated to provide more specific data regarding individual movement effects and their consequences on functionality.

Additionally, it was thought prudent to consider what changes could be made to electrode housing arrangements; given the lack of adjustment and adaptability currently available with myoelectric sockets. The effects of using socket-housed electrodes with no adjustment within the socket was therefore compared to alternative electrode attachment methods in order to provide more evidence as to their efficacy in providing functionality.

For these reasons, this thesis therefore focuses around four key investigations. The thesis initially examines the relevant literature associated with the subject area, which is presented and discussed in **chapter 2**. This chapter begins by focusing on the structure and function of the natural upper limb, and the concept of upper limb functionality and assessment. The presentation of the residual limb is described, along with causes of limb absence and amputation techniques, and how this will ultimately affect the socket fit and the acquisition of the myoelectric signal. Current prosthesis types, and socket types, are explored in detail; with a primary focus on myoelectric prostheses and the myoelectric control process. The evidence regarding potential socket and electrode movements with respect to the residual limb are also investigated and contrasted with the requirements of the myoelectric signal acquisition and control process, and with recognised best practice for myoelectric signal acquisition.

From this background evidence and analysis, the following investigations were subsequently developed and performed, which form the basis of this thesis:

1) A prosthesis-user analysis study.

This involved the distribution of a questionnaire to current and past myoelectric prosthesis users. This provided data on the levels and significance of poor myoelectric control and its relationship with socket and electrode tightness and contact security, plus

This investigation is presented in **chapter 3**. It was recognised that the potential effects of socket movement and prosthesis control are acknowledged in the literature. However, it was thought important to obtain the views and experiences of prosthesis users to gain evidence as to how they perceived these effects impacted on their ability to perform ADLs. The way of achieving this was by obtaining prosthesis users' views relating socket and electrode contact, and how this influenced prosthesis control and their ability to perform these ADLs. This chapter therefore describes the processes involved in the collection and collation of data using a specifically-designed questionnaire, and contrasts the results obtained with those from other studies relevant to this subject area.

2) An electrode contact functionality assessment.

Chapter 4 describes a pilot study which examined three different test conditions, linked to electrode housing and contact security. These conditions involved the use of myoelectric electrodes which were either, intentionally disconnected from the prosthetic socket, arranged with enhanced perceived contact security to the skin of the residual limb, or housed within the standard electrode housing arrangement. This comparative assessment was undertaken to demonstrate which test condition provided greater levels of myoelectric prosthesis control and resultant functionality. The method of functionality assessment was specifically-chosen as it was designed to include the assessment of prostheses as well as the natural hand.

This study used a validated, reliable functionality assessment procedure to contrast the effects on prosthesis control and resultant functionality from three different electrode housing conditions within the upper limb myoelectric sockets. Through using the recognised current standard electrode housing condition as the control, this study was designed to demonstrate whether discernible functionality improvements may be obtained by comparing the data

acquired from analysing the efficacy of facilitating different electrode orientations within the prosthetic socket.

3) Development of a novel bespoke electrode housing unit.

Chapter 5 describes a follow-on study which investigated various electrode-to-skin contact security and alignment test conditions via the use of a novel bespoke electrode housing unit, which allowed finite adjustments to be administered to both electrode contact security and alignment. These adjustments were assessed with respect to prosthesis control via the use of a validated, reliable functionality assessment.

This bespoke novel electrode housing unit was devised and developed to offer the possibility of altering electrode/skin contact security by facilitating positional adjustment to either end of the electrode (and therefore the electrode contacts) whilst also offering varying alignment positions. Its effect on prosthesis functionality was compared to that afforded by the current typical clinical standard using a validated, reliable functionality assessment.

4) A motion analysis study.

This study examined the effects of specific movements which were designed to represent those used during normal daily upper limb activities, and the respective changes in prosthesis load on the production of motion artefacts.

This investigation is presented in **chapter 6**. It was developed to provide an enhanced understanding of the frequency of unwanted activation of terminal device events caused by production of motion artifacts whilst performing ADLs when wearing a myoelectric prosthesis. Three reproducible upper limb movements were selected, which had previously been validated as being representative of a range of common, daily upper limb activities. Prosthesis users were asked to perform these movements whilst their myoelectric prosthesis was connected to a clinical assessment system which recorded the motion artifacts generated during each motion. A bespoke pulley apparatus was also used; with the loading mechanism attached to the prosthetic hand facilitate the use of varying loads, which were representative of those associated with normal daily activities.

Chapter 7 provides a summary and analysis of the results and the subsequent statistical analysis from each of the relevant chapters. The implications of the results obtained

are contrasted with the changing nature of prosthesis provision and the delivery of clinical myoelectric prostheses, with particular regard for Prosthetist experience and specialist expertise within this area.

1.3 *Chapter Summary*

Prosthesis control has been highlighted at recent conferences as being the key factor in increasing myoelectric prosthesis usage and functionality (43). Much of the work that has been undertaken within this field has been completed by therapists, seeking to improve functionality assessment techniques, and engineers, improving technical specifications relating to signal processing and prehensor capability (43). A need to quantify the effects of socket fit and different electrode orientations with respect to the skin, both in intimacy of contact and orientation, on prosthesis functionality, prompted the need for this thesis. There was also a need to develop a novel electrode housing to potentially improve functionality.

The research presented in this thesis is therefore primarily related to the role of the prosthetic socket, and the design of its integral parts, and the way in which each individual bespoke socket may be designed and fabricated; which is intrinsically linked to the knowledge and skill of the Prosthetist. The thesis employs specific investigations to contrast the effects of socket tightness and various parameters linked to electrode contact and orientation, with resultant myoelectric prosthesis control and functionality. Whilst there are various hypotheses cited within the text, the overall hypothesis is that myoelectric prosthesis control is adversely affected by relative movements between currently employed socket designs plus their electrode housings, and the residual limb within the socket. The null hypothesis is that the socket and the electrode housings do not significantly affect prosthesis functionality within standard socket designs.

This thesis also presents the hypothesis that when prosthesis and socket movements occur during specific daily living activities, reduced prosthesis functionality occurs, despite recent advances in myoelectric componentry. In addition, this thesis hypothesises that improvements made to the design of electrode housings which facilitate alteration to electrode orientation with respect to the skin surface within a prosthetic upper limb socket will result in improved prosthesis functionality for upper limb myoelectric prosthesis users.

Chapter 2:
The natural upper limb, prosthetic replacement and myoelectric control

2.1 *Introduction*

The natural human upper limb provides a multitude of uses and functions, making its complete or partial absence a potentially debilitating factor for any affected individual, regardless of their age, gender or social status (44-46). There are two main factors to consider with regard to upper limb absence:

1. The actual physical loss of all or part of the upper limb, and its subsequent effect on body image and symmetry, and
2. The reduction in the available levels of upper limb functionality and functional usefulness.

All human cultures exhibit a 'normalised' standard body type based on appearance, and unfortunately also a stigma of disability which may affect social interaction for many affected individuals making the cosmesis of prostheses a priority (47). Replacing the physical elements of the natural upper limb with an effective prosthesis is reasonably successful for most levels of upper limb loss; a fact borne out by the large numbers of prosthesis users who regularly wear cosmetic type prostheses (6, 7, 13-18, 20, 21, 44, 46, 48-51). However, replacement of upper limb functionality is much more challenging, with many prosthesis users abandoning functional prostheses completely (6, 48, 52, 53).

Effective functional prosthetic replacement of any natural body part requires an understanding of its structures and control mechanisms. Consequently, the first part of this chapter examines the anatomical elements and physiological processes associated with natural upper limb usage. The loss of the hand and other elements of the upper limb provide a stern challenge to rehabilitation clinicians seeking to restore functional operation and control, primarily because of the many activities and applications that may normally be undertaken using these anatomical structures. To understand the implications of upper limb prosthetic usage and restoration, it is important to recognise and realise the intricate nature of both the anatomical structures and physiological control mechanisms employed naturally within the upper limb.

Additionally, the comparative capabilities of upper limb prostheses with regard to the natural arm, particularly in replacing optimum levels of functionality, are also clearly important to this study. Consequently, the next part of this chapter examines functionality assessment methodology, modelling techniques and specific functionality assessments designed for prosthesis users that are comparable to the capabilities of the natural upper limb.

Finally, this chapter identifies and examines prosthesis designs and prosthetic components, which are currently used to replace and replicate the natural upper limb. The causes of limb absence and amputation techniques are examined, along with currently-available prosthesis types; with myoelectric prostheses and myoelectric control being the primary focus. In particular, socket design and function is contrasted with myoelectric signal acquisition, as these two areas are fundamental to the hypothesis.

2.2 *The Natural upper limb: overall structure and function*

The natural upper limb includes 32 bones and 3 major joints; the shoulder, the elbow and the wrist, along with numerous smaller joints located within the hand (54-56). The upper limb segments and major joints within the arm work in tandem with a complex control system to correctly locate and position the hand for object manipulation and activity completion (57).

The following sub-sections describe the anatomical structures, ranges of motion and functional control processes that are normally present in the natural upper limb. In addition to hand functionality, particular attention is also paid to the following:

- Joint movements and functional ranges of motion for the major upper limb joints

These play a significant part in the complex movement capabilities which are available within the natural arm, and are particularly relevant to the activities included within chapters 4, 5 and 6;

- The anatomical structure of the elbow and other upper limb joints

The upper limb joints and their respective movements must be noted as they are used to position the hand in space for daily activity task completion. The elbow in particular is

important because specific anatomical landmarks within its structure are also used suspend standard transradial prostheses;

- The muscles of the forearm.

These are used to effect movements within the natural hand, and remnants of these muscles are also used to operate commonly prescribed myoelectric transradial prostheses.

2.2.1 *The hand*

The hand is the 'end effecter' of the natural upper limb and is its most complex and functionally important structure (55). The hand consists of 27 relatively small, distinct bones which are grouped into three main categories; the carpals (located most proximally), the metacarpals (within the upper palmar region) and the phalanges (the digits) (54-56). These are manoeuvred and articulated by numerous muscles and their associated tendons, which are categorised as extrinsic (located within the forearm) and intrinsic (located within the hand) (54, 56). Movements of the natural hand have been classified as either prehensile (object held) or non-prehensile (object manipulated) (58).

In order to undertake daily living activities, the natural hand can assume characteristic and identifiable grip types, or grip patterns. Despite the numerous independent articulations available within the hand, the number of identified and distinctive hand grip types is relatively small. Two major grip types were described by Napier (1956) (58). These are the power grip (between partly flexed fingers, palm and countered by thumb), and the precision grip (between flexor aspects of fingers and thumb equally). Prior to this, six patterns of grip within the natural hand were described by Taylor and Schwartz (1955) (59). Napier's power grip may be performed using three of these patterns: the spherical, tripod or power grip. The precision grip may be achieved using a lateral, tip or extension grip (**figure 2.1**).

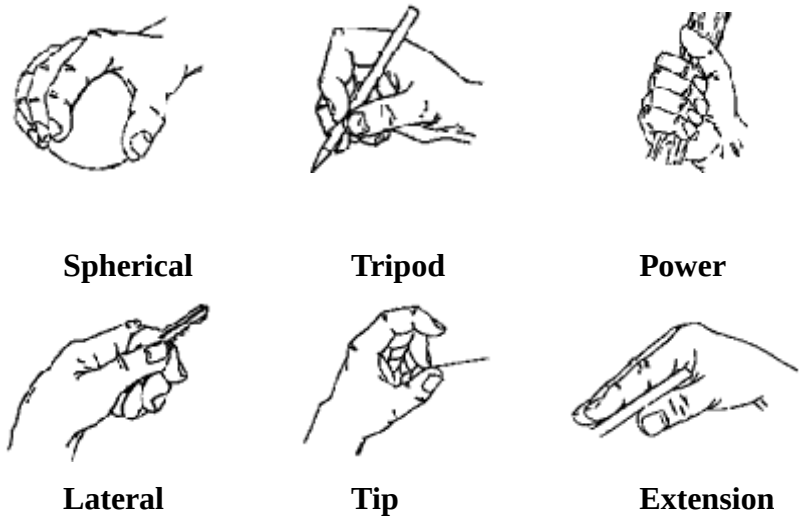


Figure 2.1: The six defined grip patterns for the natural human hand (60)

A fully-functioning natural hand is able to interchange these grip types quickly and effectively, enabling the subject to employ the hand in a variety of ADLs (section 2.18.1), with each activity requiring a different combination of grip types (57). Consequently, the effective functionality or functional capability of the hand may be determined by its speed and ability to conform to each grip type accurately and to apply this form to a requisite activity (57).

However, the hand is not merely employed as a functional tool. It is also used for social contact and physical expression and as such has a clear aesthetic value as well as a functional value (55). As a purely functional tool, the hand is actually restricted by its evolutionary and aforementioned social requirements (58). Since effective prosthesis replacement will be determined by all the above factors, these social and aesthetic considerations will have significance in terms of prosthesis design and user acceptance. Furthermore, to operate effectively, the hand must be positioned optimally during any activity; requiring coordinated movements of the wrist, elbow and shoulder joints (57).

2.2.2 *The wrist joint*

The wrist is an ellipsoid joint, which can be simply envisaged as a ‘rugby ball in a socket’, providing flexion, extension, pronation, supination, abduction and adduction but not rotation (54, 56)-see **figure 2.2**. Proximally, the wrist locates the radius and the ulna at their intersection, with the radius being the larger of the two bones at this intersection (54). In

contrast, the ulna is the largest forearm bone intersecting at the elbow (54). The radius and ulna intersect with the carpal bones at the base of the hand, forming the wrist joint, and enabling the hand to flex, extend, abduct and adduct with respect to the forearm. Pronation and supination effectively occurs at the distal radio-ulnar joint, not at the intersection with the carpals, but despite this technical anomaly pronation and supination are normally considered wrist movements (54, 56).

Movement	**Functional range of motion°**
Flexion	**54°**
Extension	**60°**
Adduction (Radial deviation)	**17°**
Abduction (Ulnar deviation)	**40°**
Pronation	**20°**
Supination	**104°**

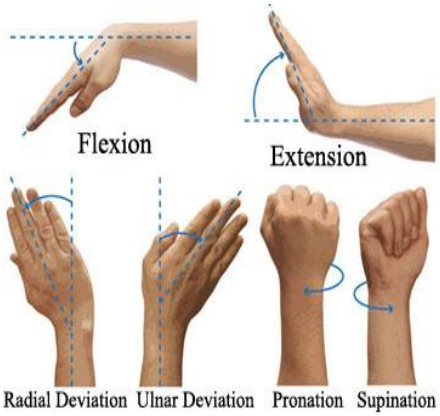


Figure 2.2(a): Functional wrist ranges of motion (61, 62) and **Figure 2.2(b):** movements (63)

2.2.3 *The elbow joint*

The elbow is a single axis hinge-type joint with a normal flexion range of between 0 degrees and 142 degrees and (within normal elbow joints) no available hyperextension (64) (see **figure 2.3**, below). The elbow and shoulder joints enable the hand and the wrist to be placed in the correct position for optimum functionality. The range of motion for individuals with a congenital limb absence will usually be slightly greater, as malformation of the elbow joint ligaments often leads to joint laxity and pronounced hyperextension of the elbow joint (66).

The elbow joint structures are particularly relevant for transradial socket fitting. The Prosthetist must contour the socket around the residual limb in order to maintain suspension (where applicable) and comfort during prosthesis usage. These aspects of socket fitting are inherently essential to the basis of this thesis and will be dealt with in more detail later in this chapter.

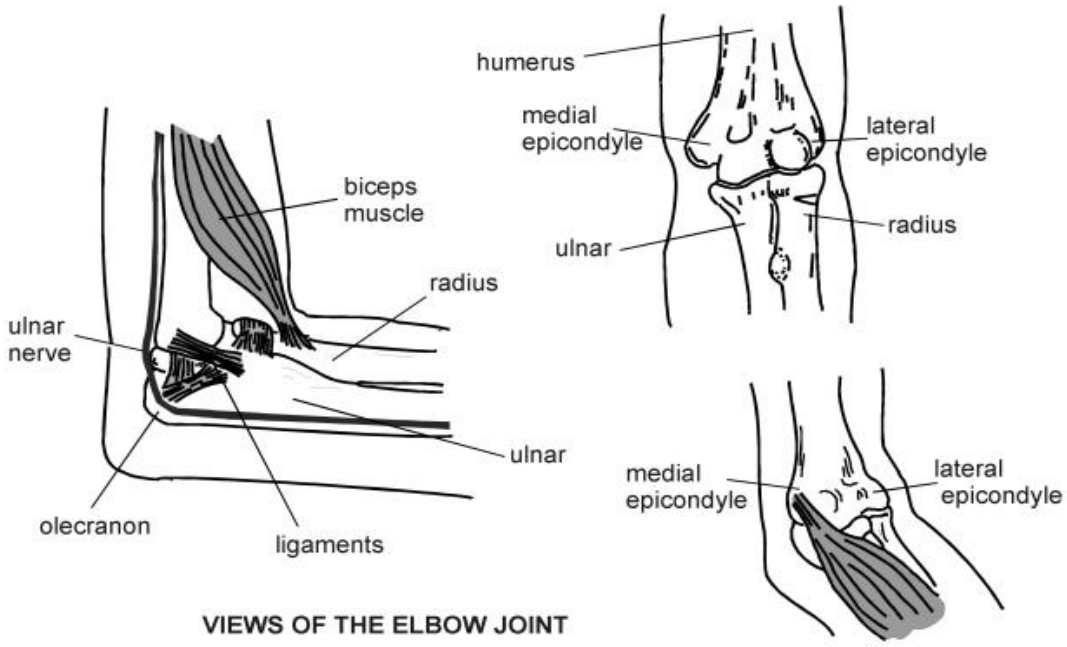


Figure 2.3: Anatomical structures of the elbow joint (65)

2.2.4 *The shoulder joint*

The relatively restricted motion of the elbow is compensated for by the extensive range of motion available from the shoulder, which is a shallow ball-and–socket joint offering abduction / adduction, flexion / extension and rotation in a traversing arc as shown in **figure 2.4**:

Movement	**Functional range of motion(°)**
Flexion	**159°**
Extension	**50°**
Adduction	**40°**
Abduction	**164°**
Internal rotation	**65°**
External rotation	**85°**

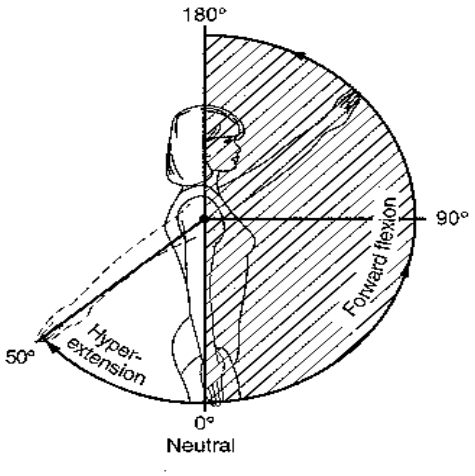


Figure 2.4(a): Functional shoulder motion (67); **Figure 2.4 (b):** Shoulder arc of motion (68)

This extended range of movement also allows the subject to compensate if either wrist or elbow movements are reduced due to injury, deformity or prosthesis movement restrictions.

2.3 *Muscle groups within the natural upper limb*

Provision of such an intricate movement capability, and to control each of the many joints within the wrist and hand effectively, requires numerous muscular insertions and an efficient control system. As a consequence, the natural forearm is distinguished by its complex muscular patterns formed from each of the many muscles required to accomplish the finite movements of the hand and wrist. This is worth noting even at this stage, since muscles which are effectively independent could provide contrasting and potentially conflicting myoelectric signals, which in turn may interfere with the potential clarity of the myoelectric activation signal.

The natural arm is effectively split into two main sections with regards to muscle groupings: the forearm section, and the upper arm section. The numerous forearm muscles used to manipulate the hand and wrist are described in **tables 2.1 & 2.2**.

Muscle	Action	Origin	Insertion
Flexor carpi Radialis	Wrist Flexion	Med. humeral epicondyle	Bases of 2nd and 3rd metacarpals
Flexor Carpi Ulnaris		Med. humeral epicondyle	Pisiform
Extensor Carpi Radialis longus	Wrist Extension	Lateral supracondylar ridge of the humerus	Base of 2nd Metacarpal
Extensor Carpi Radialis Brevis		Lateral epicondyle of the humerus	Base of 3rd Metacarpal
Extensor Carpi Ulnaris		Lateral epicondyle of the humerus	5th Metacarpal
Pronator Quadratus	Pronation of the wrist	Distal quarter of the anterior ulna	Distal quarter of anterior radius
Pronator Teres	Pronation of the wrist	Medial epicondyle of the humerus (humeral head); Coronoid process of the Ulna (Ulnaral head)	Middle and lateral surface of the radial body
Brachioradialis	Flexion/ supination of the wrist	Lateral supracondylar ridge of the humerus	Styloid process of the Radius
Supinator Brevis	Supination of the wrist	Lateral epicondyle of the humerus; supinator crest of ulna; radial collateral & annular ligament	Upper/outer surface of Radius

Table 2.1: Major muscles of the forearm, affecting wrist function (adapted from 54, 56)

Muscle	Action	Origin	Insertion
Flexor digitorum superficialis	Flexion of the proximal 2^{nd} – 5^{th} finger joints	Medial epicondyle of the humerus (humeral head); Coronoid process of the Ulna (Ulnaral head); Oblique line of the radius	Bodies of the middle phalanges of the fingers
Flexor digitorum profundus	Flexion of the distal 2^{nd} – 5^{th} finger joints	Proximal/anterior surface of the ulna / interosseous membrane	Bases of distal 2nd-5th phalanges
Flexor pollicis longus	Flexion of the thumb	Anterior surface of radius /interosseous membrane	Base of distal 1^{st} phalange
Extensor digitorum	Extension of the 2^{nd}-4^{th} fingers	Lateral epicondyle of the humerus	Extensor expansions of the 2^{nd}-4^{th} phalanges
Extensor digiti minimi	Extension of the little (5^{th}) finger	Lateral epicondyle of the humerus	Extensor expansions of the 5^{th} phalange
Abductor pollicis longus	Extension and abduction of the thumb	Rear aspect of the proximal ulna, radius and interosseous membrane	Base of 1^{st} metacarpal
Extensor pollicis longus	Extension of the thumb	Rear aspect of the ulna and interosseous membrane	Base of distal phalanx of 5^{th} phalange
Extensor indicis	Extension of the 2^{nd} (index) finger and wrist	Rear aspect of distal ulna and interosseous membrane	Extensor expansion of 2^{nd} Phalange

Table 2.2: Muscles affecting Hand grip function (adapted from 54, 56)

The wrist flexors are normally located on the medial aspect of the forearm, whilst the wrist extensors are normally located on the lateral aspect of the forearm. However, these muscles will tend to cross-over and overlap each other, making them difficult to clearly

identify from a basic examination of the forearm muscle mass (54, 56). The numerous forearm muscles present a complex layout, and are much less easily determined than the relatively large biceps and triceps upper arm muscles which flex and extend the elbow.

Following amputation or due to congenital deformity, the remnants of the forearm muscles and upper arm muscles are used to control transradial and transhumeral myoelectric prostheses respectively, and are therefore of interest to this study (69, 70, 71). However, myoelectric prostheses are not commonly used at more proximal levels, when complete upper limb absence at the shoulder has occurred, and transhumeral prosthesis usage is generally less common than transradial prosthesis usage due to the loss of the natural elbow in addition to the wrist and hand (6, 72, 73).

The mechanical change in shape of a contracting muscle is important to recognise, since this will naturally change the overall external contour, or topography, of a body part, or more pertinently, a residual limb. The prosthetic socket shape will be effectively fixed in a rigid socket, and therefore will not change to accommodate the changing shape of the residual limb. Therefore, if the residual limb changes in shape whilst encapsulated within a prosthetic socket (for instance during muscle contraction), then this will affect the stiffness of the interface, and potentially produce movement between the residual limb and the electrode which is fixed in the housing in the socket wall (42).

2.4 *The control mechanisms of the natural upper limb*

The large numbers of muscle groups that are available to move the upper limb structures and form the grip types of the hand, require an accurate and coordinated control system. This control is regulated by the central nervous system, primarily the cerebral cortex, which is the part of the brain and is able to make conscious and sub-conscious decisions initiating upper limb movements (54, 74, 75). The primary motor cortex, situated on the frontal lobe of the cerebral cortex, includes distinct regions on its surface that correlate point for point with specific areas of the body (56). The hand and arm in lie in close proximity to the trunk on one side, and to the face on the other (56).

Upper limb control, and particularly hand control, has a larger proportion of the primary motor cortex surface area dedicated to its function compared to the areas associated with the functions of the lower limbs and trunk (56). This highlights the fact that the range of

finite activities available from the hand are more numerous and complex than lower limb and trunk activities, and hence requires more ‘brain power’ for effective control.

The upper limb also receives inputs from the secondary motor cortices, located around the primary motor cortex. These are used to gauge the position of an object in space, thereby allowing the hand to reach its target effectively and quickly (54, 75). In addition, these areas of the brain determine the grip strength required to complete a task, depending on the nature of the object being targeted.

Although the initial activities using the hand are consciously controlled, the remaining factors would be performed at a subconscious level. This enables the subject to focus on other aspects of their environment without having to make time-consuming decisions about every aspect of the primary task being completed (54, 75).

These functions take place almost instantaneously, and without the subject requiring conscious control of them. For example, a subject may wish to grasp an object, but they may achieve this almost subconsciously. To control the natural hand, the central motor network also employs a ‘feed-forward’ control mode that activates separate muscles within a coordinated pattern to provide a fast and effective grip management system (74, 75). The motor control network plans the approach of the hand towards its target at a subconscious level, enabling the person to focus on one or more elements of the task, or indeed on other tasks that may be completely separate from the predetermined movement. This natural control system also employs the muscles required for task completion in groups, whereby these muscles are activated in a preordained sequence, removing the need for time consuming signals and messages to be sent to each individual muscle used (75, 76).

The following section analyses the concept of upper limb functionality and its measurement, which provides the benchmark for the provision of successful prosthesis replacement.

2.5 *Upper limb Functionality and its measurement*

Natural upper limb control clearly relies on a coordinated system that allows the user both mobility and dexterity, and wields simultaneous and virtually instantaneous responses to stimuli and requirements. When the control network, anatomical movements and physiological mechanisms are all functioning normally, the natural upper limb and hand are

very adaptable and versatile; making them adept at completing a wide variety of tasks in a whole host of various circumstances. It is this versatility and adaptability that makes the assessment of upper limb functionality very challenging. Indeed, even defining it can be seen as problematic; given the variances in each individual's requirements and applications. Light et al (1999), defined functionality as "suitability to the task", before proceeding to examine a number of prosthesis function and functionality assessments (57). The relationship between the level of functionality and any give task is not always clearly defined however, making even this correlation a potentially subjective assessment in its own right.

To assess the effectiveness of a prosthesis, there is a requirement for a 'gold standard' or benchmark against which the functional capabilities of the prosthesis may be compared. For the purposes of this investigation, the fully-functioning natural upper limb provides that standard as achieving this level of functionality is the ultimate goal of prosthetic rehabilitation. It is important to accurately determine and categorise the capabilities of the natural upper limb even though, as upper limb functionality as a concept is not easy to define. An accurate benchmark must be achieved if modern prostheses options are to be categorised and prescribed effectively, and prosthesis users are to acquire optimal functionality.

2.5.1 *Activities of daily living*

Most modern functionality assessments quantify the subject's ability to undertake specific activities of daily living (ADLs) (77). These activities are chosen because they realistically encompass the range of upper limb and natural hand activities, which would normally be employed on a regular daily basis. ADLs were first developed as a concept in 1935, but it was not until 1968 that they became a term of reference within journal articles (78).

There are a number of reasons for evaluating functionality in terms of ADLs (79):

- They provide an overview of functional status;
- They determine activity limitations;
- They establish a baseline for treatment;
- They provide a guide for intervention planning;
- They provide a guide for reporting and data management;
- They evaluate intervention programs and monitor progress;
- They plan for the future and for discharge;

- They measure outcomes of rehabilitation;
- They provide data for evidence-based practice.

Functionality assessments based on ADLs are usually preferred by therapists and clinicians, since they offer a more realistic view of the capabilities of the prosthesis user than simple, timed tests (57, 77). The disadvantages of ADL-based assessments are that they are often more difficult to measure accurately than basic tests, and may be subjective with regard to the assessor (57, 77). However, in overall terms they can offer a more accurate functionality assessment than those afforded by a singular comparative approach (57, 77). However, there may still be restrictions based on the numbers of prosthesis users that are included, due to the one-to-one nature of the assessment methodology.

2.5.2 *Alternative functionality assessments*

Other methods of assessment may involve the use of simple, timed tests, or may also involve interviews or questionnaire-based surveys. Timed tests are particularly common with regard to prosthesis assessments, but are restrictive in terms of the outcomes measures that may be achieved (57, 77). They do however provide an accurate set of data, and the testing regime can easily be repeated and is not subjective with respect to the clinical assessor (57, 77). They are useful in providing data, which specifically contrasts and compares a distinct function or functions between a select number of terminal devices or prosthetic components. However, the particular function chosen may not accurately represent upper limb functionality as a whole and therefore may be misleading (57, 77).

Questionnaires provide an opportunity to acquire information on usability and functionality from large numbers of potential recipients over a defined period of time (80). They also offer the opportunity to acquire a wide variety of information, and are completely equal between recipients in terms of the assessment structure (57, 77, 80, 81). However, the results may be interpreted selectively or inaccurately depending on the recipients' understanding of the questions as stated and their own subjectivity when providing their opinions (57, 77, 80). An inability to re-evaluate this information may also prove problematic, since ethics dictates anonymity and confidentiality for all responders. Tracking down specific subjects and responses is therefore not possible, nor potential clarification of data as received, and questionnaires should reflect actual daily activities, not perceptions

(81). However, questionnaires are an extremely useful tool for widespread population samples, and the development of a questionnaire for use as part of this study is shown and detailed in **chapter 3.**

2.5.3 *Modelling functionality assessments*

Modelling the success or otherwise of functionality assessments is clearly not straightforward, given the potentially subjective nature of functionality. Reliability and validity are key features of any potential functionality assessment tool, but are by no means the only factors requiring consideration. Fess (1986) listed the following as requisite standardised criteria which should be used in these types of assessments (82):

a) A statement defining the purpose of the test;
b) A detailed description of the equipment to be used for the assessment procedures;
c) The dissemination of normative data into appropriate categories;
d) Specific administrative / scoring instructions;
e) For validity studies, the suitability of the assessment to the task;
f) For reliability studies, the repeatability of the data from varying assessors.

Many assessments which have sought to measure functionality have not always met these criteria. Validation of assessments has been particularly problematic, given the huge variation in activities and functions employed by the natural hand within the sphere of functionality. One model used to help achieve validity of assessment is the 'Rasch' model, so-named after its originator, Danish mathematician Georg Rasch (83, 84). The Rasch model provides a benchmark for successful assessment by rating the response from each user against the ability of the user and the latent difficulty of that particular task (83, 84). An assessment that meets the criteria within the Rasch model will exhibit a proportional and rational correlation within the measurement data (83, 84). In essence, the model determines that the data must meet the model's criteria if the assessment technique is to be deemed as valid and therefore useful.

Assessment techniques and surveys which have been influenced by the Rasch model include the Orthotics and Prosthetics User Survey (OPUS) (82). This survey was correlated with the Rasch model, and certain elements were altered or even deleted to enable the assessment to conform more closely to the model and hence increase its validity. However,

there may have been some discrepancies with this assessment and its relationship with the Rasch model which were associated with language difficulties and the use of certain key words and interpretations (82).

The commonly accepted benchmark for functionality assessment verification tools is the International Classification of Functioning, Disability and Health (ICF), developed by the World Health Organisation to classify the levels of health and disability amongst subjects' worldwide (85). Ensuring that best practice standards are set is essential if functionality assessments are to achieve accurate outcomes.

These outcomes are also equally important in prosthesis user functionality assessment; having benchmarks that apply to both prosthetic and natural upper limb usage is essential if parity is eventually to be achieved. The following section examines the assessments that have been implemented for prosthesis user functionality assessment, but are still based around standard concepts that are used for the natural upper limb.

2.5.4 *Functionality assessments for prosthesis users*

Lindner et al (2010) compared functional outcome measures for 68 upper limb prosthesis user surveys with the ICF, by analysing the following (86):

1. Data extraction;
    a. Test / retest reliability;
    b. Inter-rater reliability;
    c. Intra-rater reliability;
2. Internal consistency;
3. Content validity;
4. Construct validity;
5. Responsiveness.

Using these criteria, the authors found that the OPUS survey achieved a good correlation with the ICF, as did another functionality assessment, called the Assessment of Capacity for Myoelectric Control (ACMC) (84). The latter measures the subject's ability to control myoelectric prostheses during specified daily tasks. The method employs 30 distinct tasks, based around grasping, holding and releasing. Clinical observations regarding the

capability of each subject are noted whilst the subject completes each task. Hermansson et al (2005) showed that the ACMC assessment method did, generally at least, also correlate well with the Rasch model (84). However, there were some variations, which were potentially linked to the different interpretations made by clinical assessors regarding the capabilities of each subject undertaking the respective individual tasks. The subjectivity of this assessment again highlights the difficulties associated with functionality assessment and the prospective outcomes of any assessment method.

Hermansson et al (2006) found that intra-rater reliability of the ACMC, or the reliability of scoring by the same clinical assessor for the same subject at different times, was excellent (87). However, inter-rating reliability of the ACMC, or the reliability of scoring between different assessors, did exhibit some discrepancies (87). This was afforded to the different levels of experience that each assessor had with the ACMC assessment prior to the subjects' evaluation (87).

The unique characteristics of upper limb prosthesis usage have brought into question the validity of 'standard' natural upper limb assessments when applied to their usage. Assessments, such as the ACMC, have attempted to redress this situation but the tendency historically has been for prosthesis assessments to focus on simple, timed tests, not ADLs (57, 77, 84). Often, newer prosthesis variants, such as myoelectric prehensors, have been compared with the split-hook, the latter being used as the benchmark for prosthesis functional capability (57). Meredith (1994) performed such a comparative assessment, investigating the functional capabilities of three prehensors, including a myoelectric hand and a split hook with a harness (88). The main drawback with this approach was that the split hook was not validated as the most functional device, and was not comparable to the natural hand, the latter being a more appropriate benchmark for any new prosthesis or design.

This realisation led to the development of the Southampton Hand Assessment Procedure (SHAP), which was specifically designed to enable upper limb prosthesis functionality assessment, as well as assessments of the natural hand (57, 89). The SHAP is based on selected activities of daily living (ADLs), plus a series of abstract object tasks which provide an individual assessment of each of the grip types described and illustrated in section 2.2. Although not primarily designed within the frameworks of the Rasch model, the SHAP does meet the criteria of the Rasch model because it uses a point-to-point, linear functionality

index to calculate the hand or prosthesis functionality. This is, by definition, producing an assessment that will exhibit a proportional and rational correlation within the measurement data, as required within a Rasch model.

The SHAP requires the subject to complete 26 tasks, and is completely reliant on the subject themselves to achieve this, thereby eliminating any influence that the assessor may inadvertently impart on the assessment outcome. The respective functionality of the hand is determined by a summative score, calculated from timed contributions from the individual tasks that collectively constitute the overall assessment. A fully functioning natural hand score is rated as 100 (although it is technically possible to achieve a score higher than this) (89). The lowest score possible is zero. Therefore, any functionality assessment performed using the SHAP will be scored between 0 and 100; a higher score indicates a greater level of hand functionality exhibited by the subject. The SHAP also allows the assessor to distinguish the contributions of each of the grip types within the assessment, enabling them to determine whether specific hand movements are restricted. This is useful in deciding on the course of rehabilitation that may be employed to improve the subject's hand functionality (89-92).

Each task relates to a specific grip pattern, and the SHAP assesses the contribution of each grip by recording the time taken for each task. The following formulae (equations (1) and (2), below) are then employed to calculate an overall functionality index score based on a Euclidean squared distance calculation, which is a measure of the prosthesis user functionality and combines the varying contributions of the six prehensile patterns (see **figure 2.1**), represented by 'i' (where 'i'=1-6) . The Euclidean distance 'd' is given by equation (2), where the value of 'z' is given for each of the 6 prehensile variants; see equation (1), and is a multivariate (six varying pattern contributions, with varying times) metric in each case (89):

(1) $$z_i = \frac{x - \bar{x}}{s_i}$$

(2) $$d = \sqrt{\sum_{i=1}^{6} (z_i)^2}$$

The SHAP specifically attempts to negate the effects of the other elements of the upper limb in order to achieve a functionality assessment score that is comparable to the fully-functioning natural hand (89). It is stated by the originators of the SHAP that these other upper limb elements may distort the perceived functionality of the hand, and not enable an accurate score to be summated (89). There is logic to this argument, as engineers and designers seeking to improve hand functionality require an accurate benchmark against which any 'new' design may be compared and measured.

Despite the task not being completed by the hand, it may be argued that the manner of completion is not necessarily the most important aspect of the task for many individuals. Many individuals with upper limb absence, who choose not to wear a prosthesis, acquire excellent functional skills from using and adapting other body parts, including their residual limbs, feet and even their mouth (93).

The natural upper limb, and particularly the hand, clearly provides the subject with a potential plethora of functional movements, activities and applications, coordinated and implemented via an intricate and highly responsive control system. Despite this, an amputation should not always be considered as a medical failure; particularly if the pre-amputation condition was functionally restrictive (94). Indeed, amputation should be considered as the first step on the rehabilitation pathway for many individuals with seriously debilitating conditions or injuries (94, 95).

Retaining the maximum amount of potential functionality is a key factor in determining the type and level of amputation that occurs (71, 94, 96). The following section identifies the causes of limb absence and amputation, and their ramifications.

2.6 *Limb absence and amputation*

2.6.1 *Causes of limb absence*

The unique requirements of each upper limb prosthesis user can be related to the causes of the limb absence (71, 97, 98). Unlike lower limb absence, which is primarily caused by factors associated with diabetes and cardiovascular deficiency, upper limb absence is primarily congenital or acquired through causative factors such as trauma (predominantly), sarcoma or meningitis (71, 97-102). The average age of an individual with some form of

upper limb absence will normally be less than one year old and with healthy young males the most likely to be affected (71, 94, 95, 97-100).

2.6.2 *Congenital absence*

Approximately 4 in 10,000 live births in the United States of America are affected by congenital limb absence (103). Approximately 40% result in a transradial level of limb absence, with an approximate 2: 1 majority affecting the upper rather than the lower limb (97, 103, 104). Causative factors are not clearly established, but poor diet, genetic predisposition and exposure to toxins or specific environmental conditions may predispose a congenital absence (71, 105).

Congenital absence is the commonest cause of limb absence in children under ten years of age (71, 101, 105), and generally occurs between weeks 3-8 following gestation (104). Congenital absence often requires no further surgery, and is normally transverse not longitudinal, with finger remnants or 'buds' often remaining at the most common transradial level (105).

Parents should be counselled on the effects of limb absence (99) as limb loss correlates with a lack of self-esteem in young adulthood (97), and treating congenital cases can be challenging as parents often have issues with guilt (106). However, subjects who have congenital limb absence are generally well adjusted to their body image, and will often develop individual techniques to accomplish basic daily activities without the use of prostheses (71, 93).

The congenital distribution of remaining muscle tissue will affect the ability of the affected individual to produce usable myoelectric control signals. Similarly, the surgical processes involved in amputation will determine the distribution, availability and effectiveness of the remaining muscles in much the same way (105).

2.6.3 *Levels of limb amputation and absence*

Sources vary with regard to the commonality of upper limb amputations. Esquenazi and Meier (103) state that 57% of upper limb amputations are at the transradial level, but the National Amputee Statistical Database (2006/7) suggests a much lower figure (nearer 20%)

for yearly referrals at the transradial level, and shows that the main level requiring prosthetic treatment is the transhumeral level at 25% (107).

This study focuses primarily on users of transradial prostheses following amputation, as these are the most common users of myoelectric prostheses (6, 72) but also includes information regarding transhumeral limb absence as this too is clearly an important and relatively prevalent level (6, 72).

2.6.4 *Amputation principles and surgery*

Amputation surgery will affect the rehabilitation outcome for a number of reasons. Physically, lesions, burns or other such impairments will affect the potential myoelectric signal acquisition from key musculature within the residual limb, with skin grafting also a distinct possibility (108). The decision to amputate will be made with reference to the severity of the injury, bone and tissue damage and nerve damage (71).

The indication for any amputation is to promote rehabilitation via the removal of painful, damaged or diseased tissue with a functioning, painless residual limb (94-96, 98-100, 103, 108). Saving as much of the limb as possible (particularly the elbow joint), is a priority (94-96, 98-100, 103, 108). A longer residual limb will also provide a more effective mechanical lever arm and at the transradial level, may also retain pronation and supination (71, 94-96, 103). However, the provision of a prosthetic replacement will also depend on the room that is available to fit the necessary componentry; if a residual limb is left too long, there may be insufficient space for an effective wrist unit, elbow unit or roll-on socket or liner; thus compromising the effectiveness of the prosthesis (1, 24).

2.6.5 *Amputation techniques*

The removal of damaged and unviable tissue, under carefully controlled sterile conditions, restricts the possibility of subsequent infection from occurring (94-96). The bone ends are chamfered and smoothed to prevent sharp edges from protruding into soft tissue, which could also potentially damage these tissues and possibly lead to sensitive areas that may affect the fitting of a prosthetic socket (94-96). Further surgery is sometimes required, in approximately 30% of traumatic cases (108).

Antagonistic muscles are sutured over bone, in a technique known as myoplasty, with the muscle groups anchored to each other (98, 100). This allows the muscles to contract under resistance, thereby generating the myoelectric signal that is essential for prosthesis control. Skin coverage should be complete and undamaged, but unlike muscle, skin should not be adhered to the bone (94-96). If this occurs, then any subsequent tension on the skin (from the prosthetic socket for example) may pull on the adherent area, and potentially separate the amputation scar or generally lead to discomfort for the prosthesis user (1).

Myoplasty techniques have been developed to provide an appropriate limb shape, to fixate the bone and give good kinaesthetic feedback (103). Alternative techniques such as the fillet flap may be used to preserve tissue length over the residual limb. The fillet flap technique uses tissue from the amputated forearm to provide distal cover over the bone ends (109).

Equal skin flaps are generally recommended with a residual limb that is hemispheric and non-bulbous (except for wrist and elbow disarticulations, where the bone ends may be employed for prosthesis suspension) (94-96, 110). In some instances, muscle tissue is insufficient to cover the bone ends; in these cases muscle tendons may be used, although the lack of soft tissue bone end coverage that results may require relief at the distal end of the prosthetic socket prior to fitting (94).

In the USA, children account for less than 10% of all upper limb amputations (94). In this case, the epiphyseal growth plates are generally preserved wherever possible. However, for amputations at the transradial level, bony growth is often restricted; whereas at the transhumeral level overgrowth may occur, even requiring bone resection in some cases (99). It is worth noting that children are often provided myoelectric limbs because of parental pressure, as well as the fact that they have a propensity to learn that diminishes with adulthood and older age (73). The growing residual limb however means that socket fitting and replacement, and above all the achievement of a suitable fit, is inherently challenging for the Prosthetist. Maintaining both the child's, and the parent's, expectations from the prosthesis may be difficult to achieve, even for the most experienced Prosthetists.

2.7 *Prosthetic rehabilitation*

The quality of the amputation, its underlying causes and the resulting residual limb that presents will have a key bearing on the success of the fitted prosthesis and the potential for successful rehabilitation. Psychologically, the nature of the injury, delays in healing and the unrealistic expectations noted above, for both children and adult potential users, with respect to the prosthesis replacement will all impact on the overall rehabilitation outcome to varying degrees depending on the circumstances and the individual concerned (97, 100).

A number of professional staff will be involved with the rehabilitation of potential prosthesis users, along with the Prosthetist. Within the United Kingdom, a consultant in Rehabilitation medicine will normally oversee the rehabilitation process for each potential prosthesis user, and will usually be joined by the respective Prosthetist, an Occupational Therapist, a Nurse and a Physiotherapist. Other professionals, such as counselling staff, may also be involved within the rehabilitation process. For upper limb prosthesis users, the role of the Occupational Therapist is particularly pertinent, along with the Prosthetist, especially with regard to rehabilitation planning and prosthetic training. The relatively large number of journal articles and papers written on the subject of upper limb prosthesis assessment, by Occupational therapists from around the world, add credence to their involvement within these processes (19, 45, 46, 48, 49, 77, 84, 86, 87, 90). The role of the Rehabilitation Consultant should not be underestimated either, and these individuals have contributed greatly to the groundswell of literature and prosthetic analysis that is currently available (21, 71, 110).

Anecdotal evidence suggests that introducing potential myoelectric prosthesis users to current myoelectric prosthesis users, within similar age groups and limb absence levels, assists the multi-professional team with respect to prosthesis rehabilitation. Multi-professional team working has been shown to greatly enhance the quality of the rehabilitation available for the potential prosthesis user (4, 71). It is essential that the Prosthetist contributes effectively to research processes within upper limb prosthetics, in tandem with other health care professionals, to ensure that appropriate developments are provided to upper limb prosthesis users (43).

Significantly, the remaining muscle groups within the residual limb of the prosthesis user are still under voluntary control, albeit without the obvious visual cues associated with

their original functions. Prosthetic training is therefore used to enable many prosthesis users to become adept at controlling these remaining muscles, thus theoretically enabling them to be able to operate a myoelectric prosthesis.

The provision of a suitable prosthesis relies upon the effective decision making of the rehabilitation multi-professional team with regard to the specific requirements of the potential prosthesis user. The actual production of a well-fitting socket however relies solely on the skill of the Prosthetist to carry out a suitable clinical casting and assessment process, and a requisite cast rectification. The socket must also be constructed and manufactured to suit the other appropriate prosthetic components that have been decided upon by the rehabilitation team (4). The first stage in this process is to produce a three-dimensional model of the residual limb. This process is briefly outlined below.

2.8 *The Upper limb Prosthesis socket*

2.8.1 *The casting and rectification process*

The Prosthetist will need to accurately reproduce the residual limb in the form of a three-dimensional model, in order to manufacture a socket which closely matches its shape and volume. This is essential for correct prosthetic fitting (1, 3, 24, 36). Normally, a plaster of Paris cast of the residual limb, called the 'negative plaster cast,' is taken and the residual limb's anatomical structures are marked on a casting sock prior to the application of the plaster bandages (111). Depending upon the type of socket being prescribed, the residual limb will be positioned in the correct casting angle, and the Prosthetist will apply suitable amounts of pressure over the areas that are to tolerate more of the prosthesis load. When the cast will lead to the provision of a myoelectric socket, the Prosthetist will also assess the remaining musculature for suitable signal strengths, and will contour the cast appropriately over what will be the electrode sites within the finished socket. It is essential for optimum prosthetic fit that the Prosthetist has suitable levels of experience for this task (4, 112).

The negative plaster cast is filled with liquid plaster, producing a three dimensional model of the residual limb, called the 'positive plaster cast'. The Prosthetist will contour and shape this positive cast to create the necessary shape for successful fitting, including the areas required for electrode contact.

The prosthetic socket will then be manufactured over this positive cast, thereby creating an intimate interface with the residual limb.

2.8.2 *Upper limb socket types*

There are a number of socket types that have been developed, but most have similar basic characteristics and requirements. Before examining the specific requirements for myoelectric prosthesis sockets, it is worth noting the generic factors that are also required for all sockets (23, 24, 25), which will now be detailed.

2.8.2.1. *Enclosure and protection of the residual limb*

Many residual limbs have sensitive areas or vulnerable tissue that may be prone to further damage or pain if left unprotected. A correct socket fit is therefore imperative to reduce levels of discomfort (113, 114). Some sockets include either soft liners, which are usually separated from the hard outer socket, or soft linings that are secured within the inner surface of the socket, or soft fabric socks (115). All of these options may increase sweating. However, they are particularly useful if the residual limb has scarring, which is more common among those prosthesis users whose limb absence was caused by traumatic injury (71, 98, 108).

2.8.2.2 *The capability of connecting other elements within the prosthesis*

The socket will often provide the attachment point for other components, such as a forearm unit in transradial prostheses, or an anchor point for a harness and / or a control cable for body-powered functional prostheses. The prosthesis user may place the cosmetic hand, active terminal device or other prehensor into the desired position via the residual limb‘s interface with the socket (23).

2.8.2.3 *Provision of proprioceptive feedback*

The prosthesis user can acquire feedback regarding the position of the terminal device or forces generated during usage of the prosthesis via the residual limb/socket interface (113). This is useful for all prosthesis users, but particularly for those with impaired vision. Proprioceptive feedback is also listed as one advantage of body-powered prostheses (6, 14, 45, 46).

2.8.2.4 *Distribution of the prosthesis load*

The prosthesis will place a load on the residual limb, which will vary depending on the weight of the prosthesis and its relative applications. Usually, a cosmetic prosthesis will deliver fewer loads to the residual limb than a functional prosthesis, because it is lighter, and is not employed for active prehensile tasks. However, when a harness is employed, this will absorb the majority of the load that is generated from body-powered prosthesis usage (45).

2.8.2.5 *Prosthesis suspension*

Upper limb sockets which provide prosthesis suspension may remove the need for a harness when used within cosmetic and myoelectric prostheses at the transradial level (28, 37, 116). It is worth noting that there is a substantial difference between the weight of a typical cosmetic prosthesis and a typical myoelectric prosthesis; the latter being substantially heavier (117-119). This means that providing effective suspension is inherently more difficult within a myoelectric socket; particularly if the residual limb is relatively short with the incumbent lever effect of the prosthesis acting on the socket. The weight of the prosthesis will be concentrated within the myoelectric hand, which will be at the distal end of the prosthesis, and therefore the load on the residual limb will also be increased.

2.8.2.6 *Functional prosthesis operation*

Sockets within myoelectric prostheses will normally house the electrodes which are used to control the prosthesis, or in some cases electrical touch switches (although these are far less frequently employed, and are normally only used in prostheses for more proximal levels of limb absence) (40, 70, 72, 120, 121). The prosthesis user will require conscious control of at least one muscle group within the residual limb in order to be able to operate a myoelectrically-controlled prehensor or other terminal device using these socket-housed electrodes.

2.9 *Socket design and construction*

In order to provide the necessary functions outlined above, the upper limb prosthetic socket requires certain fundamental design and construction features. The basic socket design for upper limb prostheses, taking into account the requirement to provide the functions detailed in sections 2.6.1 to 2.6.4, will enclose the residual limb and sensitive parts of the body that have been exposed due to amputation for protective purposes (23). In doing so, these areas in contact with the skin will provide the proprioceptive feedback for the prosthesis

user; albeit through a soft lining/liner if this is applicable (113, 115). For the socket to keep its shape over the residual limb and to provide a secure fastening for other elements of the prosthesis there is a requirement for it to have rigidity within its construction (42). The distribution of prosthesis load will also demand a rigid interface in all but the lightest of usage.

2.9.1 *Socket manufacture*

The majority of upper limb prosthesis sockets consist primarily of composite thermosetting plastics, and are manufactured via a process known as lamination (111, 122). In this process, layers of nylon stockinet are applied over the relevant positive plaster cast, which should be an accurate model of the prosthesis user's residual limb. These layers of stockinet provide the tensile strength within the socket, and are covered with a polymer resin that becomes rigid during the lamination process via the addition of a chemical catalyst (111, 122). The resin provides the socket with increased compressive strength and the nylon / resin mix is vacuum formed over the plaster model for accurate replication (111, 122).

The composition of the socket may be altered to suit the requirements of the prosthesis users' applications and aesthetic considerations; for example, thin walled sockets are provided for paediatric individuals, allowing more flexibility for residual limb growth (123).

When a myoelectric socket is being manufactured, the lamination process will also include the addition of 'dummy' electrodes which are secured to the positive plaster cast prior to socket manufacture. These will create secure electrode housings, which enable the electrodes to fit intimately within the socket walls. More detailed information regarding these electrode housings are provided in **chapters 5 & 6**. It is worth noting at this point that these housings are inherently fixed within the socket wall, and will be subject to the same movements which occur between the socket and the residual limb during usage.

2.9.2 *Protective elements of the socket*

Many upper limb prosthesis users with limb absence caused by traumatic injury may have sensitive or scarred tissue covering all or part of their residual limb (71, 103). This tissue may be particularly vulnerable to loads generated by prosthesis use, albeit that these loads will normally be much smaller than those generated within lower limb prosthesis

sockets (113, 114). Wearing socks or using soft linings will again protect against chafing and discomfort (115), and will be compatible with cosmetic prosthesis usage and body-powered prosthesis usage (1).

2.9.3 *Socket contouring and suspension*

The socket must be contoured around the remaining elements of the residual limb and, within standard sockets as previously described, pressure must be applied only to those areas that can tolerate loading, such as soft tissues, particularly if no socks are being worn (25, 124). The hard nature of the plastic socket will clearly be uncomfortable for the prosthesis user if direct loads are applied over the bony prominences or other sensitive areas (124). However, the Prosthetist must still endeavour to produce a plaster model that distributes the pressure imparted by the prosthesis in the most effective manner even if socks are worn over the residual limb (36).

If the socket is contoured effectively, suspension may be afforded for some levels of limb absence if the correct shape and volume match is produced (28, 37, 116, 124). Specific socket types for the most common levels of limb absence are detailed later within this chapter, but sockets which have been specifically designed to improve suspension across most levels of limb absence are now available and are clearly of relevance to upper limb prosthetic replacement.

2.9.4 *Transradial socket variations*

Most current transradial prostheses incorporate anatomically self-suspending sockets primarily because these remove the need for an external harness (28, 37, 116). Prior to 1960, transradial prostheses were almost always used in conjunction with a harness and incorporated a type of socket called a ‘cup socket’ that did not extend beyond the humeral epicondyles and the olecranon (4).

The need for a harness to provide suspension was an inherent disadvantage for previous types of upper limb prostheses, since the harness was often described anecdotally as restrictive, uncosmetic and uncomfortable (6, 14-18). These factors led to the development of self-suspending sockets, which were most successfully employed at the transradial level of limb loss. The first of these was presented in 1959 by Hepp and Kuhn in Copenhagen, Denmark, and was referred to as the ‘Munster’ socket; following its development in Munster,

Germany (28). The ‘Munster’ socket employed higher proximal trim lines than the standard cup sockets that had been previously used for transradial prostheses. The anterior trim line enclosed the biceps tendon, and the socket was indented either side of this. A posterior counterforce was provided with an equally high posterior trim line that enclosed the olecranon and indented above this bony prominence (28, 116). The socket was cast at an angle of 90 degrees which, in tandem with the socket impressions previously described, provided suspension for the attached prosthesis; even though the range of motion at the elbow was considerably restricted (28, 116).

The ‘Munster’ socket was the first self-suspending transradial socket, and thus was the first to be incorporated within cosmetic upper limb prostheses (116). This was extremely significant, since many users had not adapted to functional prostheses, and would perform many tasks without employing their prosthesis at all (6, 93). In addition, subsequent studies demonstrated that the cosmetic prosthesis, despite its name, could be used to provide a range of passive functions that would meet the functional requirements of many prosthesis users (6, 7).

Problems with the limited flexion range available at the elbow when wearing the Munster type socket were subsequently improved by the introduction of the ‘North-Western supracondylar’ socket in 1972 (37). This socket did not enclose the biceps tendon at all, but had a relatively low anterior trim line that provided the user with a full range of elbow flexion. Instead, the suspension for this socket came to a large extent from the higher medial and lateral trim lines, that extended up, and indented over, the medial and lateral humeral epicondyles either side of the elbow joint. The posterior trim line also enclosed the Olecranon, but was significantly shallower, indenting and finishing a mere finger’s width above the superior border of this bony prominence. The socket was again cast at 90 degrees. Although the lower posterior trim line did provide slightly less restriction to elbow extension, in reality elbow extension was still significantly restricted.

The casting angle and the trim lines above the olecranon contributed to the excellent suspension afforded by both of these sockets, particularly the ‘Munster’ socket. The ‘North Western supracondylar’ socket, because of its low anterior trim, is recommended for prosthesis users whose residual limbs are at least 55% of the length of the natural forearm

(37). By contrast, the ‘Munster’ socket is recommended for shorter limbs, primarily due to difficulties with donning and doffing (116).

It was this lack of motion available at the elbow that prompted Prosthetists in the United Kingdom and elsewhere to modify the ‘North Western supracondylar’ design, and create a ‘hybrid’ socket. The principle was simple; reduce the casting angle to between 60 and 70 degrees, not 90 degrees, and increase the height of the posterior wall and the anterior trim line to compensate for the reduction in suspension that would occur by reducing the casting angle. In this way, shorter residual limbs could potentially be accommodated. Suspension is reduced slightly by these changes, but unlike the previous socket variants described, the ‘hybrid’ socket is successfully employed on a range of residual limb lengths, although evidence for this particular socket is very much anecdotal. Other hybrid designs, using similar principles, have been postulated by Radocy and Brown (1986) (125), Lake and Dodson (2006) (126), and Sauter (1986) (127).

Many prosthesis users have readily accepted prostheses with a slightly looser fit, as this also provides an increase in the range of motion, and a more natural appearance. This is particularly important for those wearing light cosmetic prostheses, where aesthetics is the most important factor. It should be noted however that for all these designs, the Prosthetist must be skilled in producing sockets that match the specific user requirements. Prior to the 1990’s, in the UK a plaster technician would normally complete the rectification process, but this is now undertaken entirely by the Prosthetist (128).

2.9.5 *Transhumeral socket variations*

At more proximal levels of limb absence, such as at transhumeral level, there are normally no natural anatomical landmarks available for suspension, and therefore most sockets will require a harness for suspension. In a few cases, the fleshy residual limb that often presents at this level is suitable for suction suspension, but problems with donning and doffing the prosthesis often prelude this option. The socket fit for transhumeral prostheses, when provided in conjunction with a harness, tends to be looser than transradial self-suspending sockets, due to the lack of relatively hard anatomical structures around the transhumeral residual limb. As a consequence, transhumeral prostheses may be more susceptible to relative movement with respect to the residual limb than transradial prostheses.

At the transhumeral level, the socket of choice for most prosthesis users is a simple 'cup' socket, with extended wings around the shoulder to prevent rotation around the joint, and hence maintain the hand and elbow in both a functional and aesthetic position with respect to the torso (2, 23, 25, 126). The extension of the socket wings will normally be increased if (i) the residual limb is relatively short, due the increased lever effect and the potential subsequent motion of the prosthesis around the residual limb, or (ii) if the prosthesis user has a heavier limb prescribed, or (iii) if the prosthesis user employs their prosthesis in activities which may apply greater loads to the residual limb / socket interface (2, 23).

2.10 *Socket movement with respect to the residual limb*

Movement between the socket and the residual limb is well documented in lower limb prostheses; particularly when a sock is worn (114), but less so in upper limb prostheses. Using a sock does reduce the friction, particularly when made from cotton and silk with lower coefficients of friction than wool or nylon, and also cushions the skin (116). However, a well-fitting socket is still essential as sock cushioning will not prevent chafing and subsequent discomfort if the socket is not contoured effectively (28, 36, 37).

The stiffness of the interface between the socket and the residual limb will vary depending on the nature of the remaining tissues within the residual limb (42). The designs of many prostheses assume a rigid socket / residual limb interface, but this is not true in practice (42). The residual limb will consist of many individual structures; some, such as the bony anatomy, will be rigid, but these will also be surrounded by softer tissues, such as the muscle remnants. Muscle tissue is firmer when used regularly, and will naturally become looser and softer as the muscles within the residual limb become atrophied through effective non-use.

The stiffness of this interface will therefore be reduced as the relative amount of soft tissue within the residual limb increases (114). Consequently, for a residual limb of any given volume, an increased amount of softer tissues in the residual limb will potentially lead to more slippage between this and the socket if the socket volume is not reduced accordingly (130). However, reducing the socket volume, thereby promoting a tighter fit at the interface, may not always be practicable; if the socket is more intimately fitting then daily prosthesis usage, even donning and doffing, may become more difficult and some prosthesis users may find this unacceptable (14, 18).

Younger prosthesis users will usually have increased levels of stiffness at the interface, as the tissues retain more of their original elasticity, and the muscles are naturally firmer (114). In addition, socket stiffness will be affected by socket length; a longer socket will increase the stiffness of the interface (42), hence the reason why increased residual limb length will result in better prosthesis suspension**.** Removing the posterior quadrant of the transradial sockets around the olecranon has little effect on the security of the socket fit according to Sauter (1986) (129). However, placing medial or lateral windows in the socket at transhumeral level has been noted to decrease socket interface stiffness (42). Factors such as these, where removal of certain areas of the socket affects interface stiffness and subsequent socket suspension, is important to this thesis, since myoelectric electrodes are normally secured within exposed housings that effectively remove small parts of the socket (72).

Increasing socket suspension and interface stiffness can be achieved by using suction suspension, which is well documented at the transfemoral level of limb absence (132). Employing suction suspension in upper limb prostheses is much less common, with donning and doffing being problematic (23). In addition, suction suspension is most effective over relatively soft tissues of uniform consistency, as is the case with many transfemoral residual limbs (132). For the transradial residual limb, the existence of significant bony prominences prohibits the firm application of suction suspension around the elbow joint anatomy (**figure 2.3**). If these areas are avoided, and the socket is fitted distally to the elbow joint, then the suction imparted, particularly on short residual limbs, may not be sufficient to retain prosthesis suspension. In addition, donning the prosthesis in the correct position may be challenging for the prosthesis user employing one arm for the task.

The dual challenges of improving suspension and retaining comfort on residual limbs with varying tissue structures and consistency led to the development of the roll-on socket (131). First introduced by Ossur Kristiansen in the late 1980's, this socket has produced many derivatives and now provides a method of positive suspension for many prosthesis users (131). Kristiansen's socket, named the Icelandic Roll-On Silicone Socket, or ICEROSS, after the country of his birth, became clinically available in the early 1990's. The ICEROSS socket differed from anatomically-suspended sockets by incorporating a volume-match, quasi-hydrostatic philosophy. It also distributed the load evenly across the residual limb, rather than relying on targeted areas of loading that had been used previously (133). The employment of

a silicone-based material, which provides resistance to shear forces and comfort to the user, has made the roll-on socket one of the most significant prosthetic developments in recent times (134).

Roll-on sockets, like the ICEROSS, are available in a range of sizes to meet user requirements (131, 132, 134). The suspension created by the quasi-hydrostatic volumetric system results from the selection of a suitable socket size, which rolls snugly over the residual limb creating a stabilised balance of forces between the pressure exerted by the socket on the residual limb, and the resistive pressure exerted on the socket by the fluids within the residual limb (131). This system provides a very secure contact between the residual limb and the roll-in socket (131, 132, 134). The socket must of course be comfortable and relatively easy to apply, and a correct socket choice is made by the Prosthetist using measurements of the prosthesis users' residual limb (131).

Employing a socket that improves suspension is clearly a distinct advantage, and some upper limb prostheses users now use roll-on sockets with positive results (25, 34, 35, 135). However, roll-on sockets can induce excessive sweating, leading to problems maintaining skin hygiene, and can also, like suction sockets, be difficult to don and doff for some users with impaired upper limb mobility or absence (136).

The socket is clearly fundamental to the success of the prosthesis and the Prosthetist faces many challenges in ensuring that the socket fit is appropriate and practical for the upper limb prosthesis user. In addition, the Prosthetist will also have to select other appropriate elements and devices that will make up the rest of the prosthesis. These are briefly outlined below.

2.11 *Connective elements and other devices*

The socket is connected to other elements within the prosthesis via either a forearm laminated section in transradial prostheses, or an upper arm laminated section in transhumeral prostheses (23). These in turn are either connected to a wrist or elbow unit respectively (23). In cosmetic prostheses, the wrist units are normally immobile. In body-powered or myoelectric prostheses, they are normally manually adjustable using the remaining natural hand (1, 23).

In some myoelectric transradial prostheses, a myoelectrically-controlled wrist unit may be fitted in addition to a myoelectric hand, offering longitudinal rotation at the wrist (137). Similarly, in transhumeral prostheses, an electrically-powered, myoelectrically-controlled elbow unit may also be fitted (72). However, these units add extra weight and provide complications to control options for prosthesis users when allied to myoelectric hand control (12, 15-17). Most functional, body-powered elbow units are lighter and provide similar ranges of flexion and extension to the natural elbow; although this is usually provided in pre-set increments of approximately 15 degrees each (23). The use of a body-powered elbow unit will however require the addition of an external harness to the prosthesis (1, 23).

2.12 *Prosthetic hands and terminal devices*

Most prosthetic hands, including most myoelectrically-controlled hands, have only one degree of freedom (138-141). The grip type is normally tripod, with the index and middle fingers moving in opposition to the thumb, as seen in the Otto Bock Dynamic plus (142). Some more recent myoelectric hands, such as the “i-limb ultra" from Touch Bionics (143), offer multiple degrees of freedom, and are able to recreate more of the grip types associated with the natural human hand (140). However, these newer hands inherently require more complex and, significantly, more reliable control systems if their potential is to be realised for the prosthesis user (43). Currently, levels of functionality acquired from the latest myoelectric hands compared to the standard types show no significant improvement (8).

The split-hook is usually employed within body-powered prostheses, and provides the user with greater visual cues for simpler operation and usage (144-147). Myoelectric hands, and hooks, offer a potentially more powerful grip and a wider opening span than body-powered split-hooks (88). However, they are heavier, and as this weight acts at the distal end of the prosthesis; the lever effect amplifies the applied load, imparting greater loads on the socket/skin interface and tending to move the socket with respect to the residual limb (113).

2.13 *Upper limb prosthesis control mechanisms*

There is no active control mechanism associated with cosmetic prostheses since these have no prehensile capability (7, 148, 149). However, active control systems are present in both body-powered and myoelectric prostheses (1, 23).

2.13.1 *Body-powered prosthesis control*

Body powered prostheses, which are classed as functional devices, require the use of a harness, usually made from nylon webbing, and either a nylon or steel control cable which transfers forces generated from distinct and selected body movements to operate a prosthetic component, such as the split-hook (1, 23). A body-powered prosthesis includes a wrist unit (usually a single-knob wrist rotary) that allows for the interchanging of various functional terminal devices (23). The mechanical harness, which extends across the back of the prosthesis user, is anchored around the axilla on the sound side for unilateral prosthesis users, or both axillae for bilateral prosthesis users (4).

The harness suspends the socket and the attached forearm and componentry and also provides a mechanical means of operating the prosthetic terminal device (**figure 2.5**) (4). Socket movement relative to the residual limb was restricted by means of the attached harness, although slight motion between the socket and the residual limb would not usually be problematic (13).

Although a mechanical hand may also be inserted into the wrist unit, a split-hook is still the active terminal device which is most popular with prosthesis users, as it provides better visual cues when performing finite tasks and is easier to control and manipulate. The split-hook can either be voluntary opening (opened upon exertion) or voluntary closing (closed upon exertion) (4). The split-hook is however, particularly un-cosmetic, and the prosthesis as a whole is considered unacceptable by many prosthesis users (6).

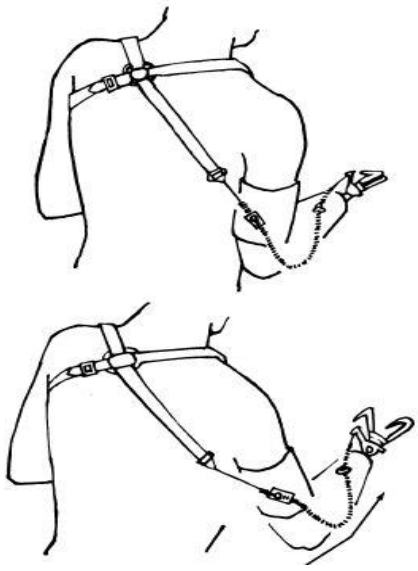


Figure 2.5: Transradial unilateral prosthesis with body-powered split-hook and harness (150)

Despite their aesthetic limitations, body-powered prostheses do have particular advantages (19, 126, 138, 145), which include:

1) Provision of a consistent and proportional response to body movements;
2) They have a durable construction and a simple design;
3) They are relatively quick and easy to operate;
4) They allow access to a range of interchangeable terminal devices, which have numerous applications.

Many surveys suggest that body-powered prostheses are still considered by some prosthesis users to be the most functional type of prostheses, and are more often employed by bilateral users where there is no functioning natural hand to perform intricate tasks (6, 14-18). They are, however, very old in design, dating back to the turn of the 20th century, and are therefore not very technologically-appealing particularly for younger prosthesis users, as well as being cosmetically poor (149).

2.13.2 *The development of myoelectric control*

The inclusion of functional capabilities within upper limb prostheses without the requirement for a cumbersome harness was a key factor in the development of myoelectric prostheses (26, 27, 151). In addition, the thalidomide tragedy of the late 1950s and early 1960s spurred on myoelectric prosthesis development (70).

Prior to the development of myoelectric prosthesis control, the only functional control alternative to a body-powered prosthesis was pneumatic control. Marquardt (1965) described an example of such a system, which initially provided successful outcomes with the small number of volunteer prosthesis users (152). However, the disadvantages of the pneumatically-controlled prosthesis included its weight, the cumbersome pneumatic cylinders and the noise created by these cylinders when activated (152).

The first myoelectric control systems were developed within continental Europe in the aftermath of the Second World War; although it was not until the late 1960s that the first usable clinical myoelectrically-controlled prostheses were developed (153). At this time, there was a widely held consensus that myoelectric control would significantly improve the functionality of upper limb prostheses (26). It was generally anticipated that future

improvements in electrode technology would eliminate problematic motion artefacts (which had already been highlighted as a potential problem with regard to prosthesis control) (26, 27). In addition, it was felt newer myoelectric prostheses would incorporate control systems that would allow the prosthesis user to feel that they had complete control of the myoelectric prehensor, as well as eliminating any elements that could hinder effective prosthesis operation (29).

2.13.3 *The myoelectric prosthesis control system*

A typical myoelectric prosthesis control system is illustrated in **figure 2.6**. The power for the myoelectric hand is provided by rechargeable batteries, which are normally rated at 6 volts, which may be inserted into the forearm or upper arm of the prosthesis; depending on which level of limb absence is being replaced, or carried separately within a concealed battery pack.

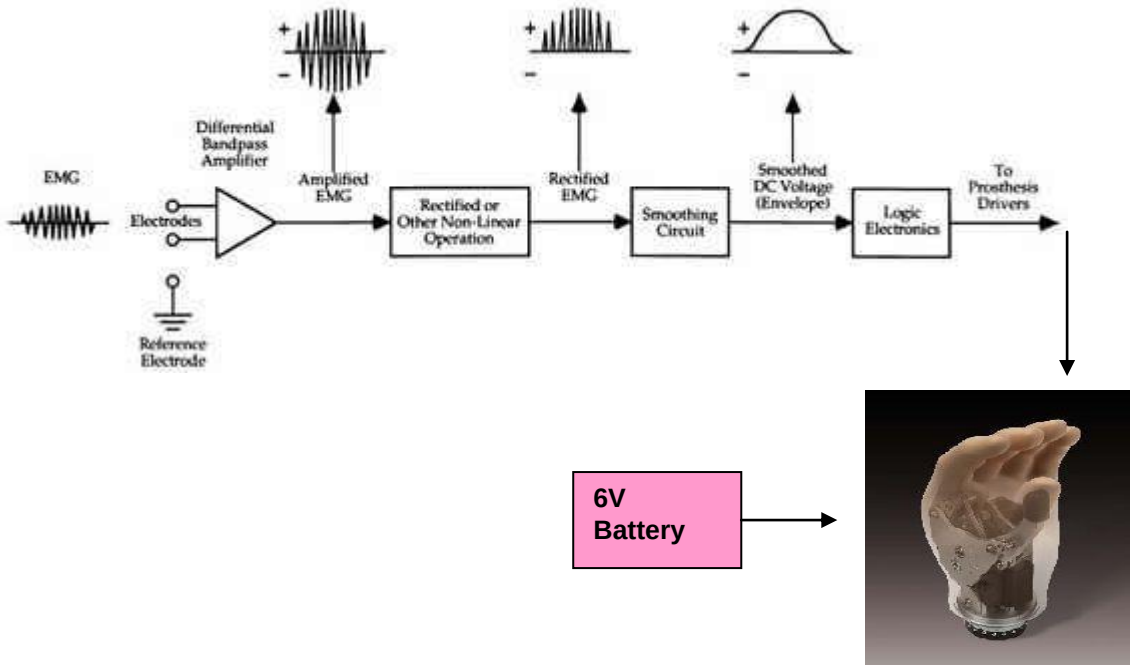


Figure 2.6: The myoelectric prosthesis control system (adapted from 154, 155)

The myoelectric signal is acquired and amplified at the surface of the skin by differential electrodes, located ideally over the apex of the muscle bulk presented (39, 40). The signal is rectified, to create an overall positive measurable signal and then smoothed (39,

40). If it is large enough (usually more than 15 micro-volts), it will produce a response from the myoelectric hand (39, 40). The processes involved have a key bearing on the subject area of this thesis and are therefore examined in more detail in the following sections.

2.13.4 *Generation of the myoelectric signal*

The electrical activity which results in the production of the myoelectric signal starts within the Central Nervous system (CNS), when the individual makes a conscious decision to contract the particular muscle of interest (157, 162). Muscles which are controlled in this manner are called skeletal muscles (56, 162). The muscular movement starts with an electrical nerve impulse which is delivered via motor neurons. A motor neuron consists of a main cell body, which lies within the spinal cord of the CNS, and an axon which is usually a very long, thin cord-like structure termed the nerve fibre (56, 162). The specific type of motor neuron that innervates skeletal muscle is called a somatic motor neuron (56).

The junction between the axon terminal and the muscle fibre is called the motor end plate (156-160, 162). Following an electrical impulse being transmitted along the length of the axon and received at the motor end plate, a number of physiological changes occur.

When a muscle fibre receives a nerve impulse at the motor end plate, also termed the neuromuscular junction, a number of changes are triggered. The impulse is easily transmitted from the axon to the muscle fibre, since both are relatively simple, tubular structures with selectively permeable membranes (158, 160, 163, 164).

Within the fibre itself, and outside its semi-permeable membrane, there are a number of ionised elements, in varying proportions, the most important being sodium, potassium and calcium. Potassium will be more greatly concentrated inside the fibre itself, whereas sodium and calcium will be more greatly concentrated outside the fibre. This variation in proportions will lead to a tendency for both solutions to diffuse into each other, thereby equalising the concentrations both within and outside the fibre. However, there are four biological mechanisms which will prevent this (160, 161):

1) Membrane permeability: the selectively permeable membrane will not allow the sodium ions to travel into the fibre.

2) Membrane polarisation: The membrane has a naturally negative charge, repelling other negative charges.

3) Charged ions within the sarcoplasm: Large charged protein ions within the sarcoplasm, or inside the fibre, which are effectively immovable, will attract charged positive ions and repel negative ions. This will naturally result in the overall charge across the *whole* structure being zero-however, the two solutions either side of the membrane will actually have different net charges (the charge inside will be positive, the one outside negative) and therefore will be polarised with respect to each other.

4) The sodium-potassium pump: This is an active process requiring energy, from Adenosine Tri-Phosphate (ATP), that transports potassium ions and sodium ions in differing proportions across the membrane, effectively helping to create a potential difference across the membrane.

These factors will produce a charged, polarised membrane, which is approximately 90mV inside the fibre with respect to the outside (160). This potential difference is due only to the distribution of the potassium ions, since the sodium ions cannot pass through the membrane. The exact potential developed by the potassium ions with respect to the different sides of the membrane, called the trans-membrane potential, can be derived from the *Nernst equation* (below) (160, 161):

$$V_m = \frac{RT}{F} \times \log_{10} (K_{in}^{+} / K_{out}^{+}) \approx 90mV$$

Where: V_m = Trans-membrane potential (Volts);
R = Universal gas constant;
T = Absolute temperature (degrees Kelvin);
K = Potassium ions (+ / -).

The Nernst equation relates the numerical values of the electrical gradient with the concentration gradient (in this case that of the potassium ions) that balances it, and is the basic formula for electrochemical cells. Essentially, the chemical processes are being converted into an electrical output (160, 161).

However, since the overall charge, including the negative protein ions within the sarcoplasm, is zero, the charge that would be detected by an electrode would again be zero if it was simply placed over a resting muscle fibre (160, 162). It is only when the fibre receives an impulse from the axon via the motor end plate that an electrical signal may be acquired (160).

Within the motor end plate, there are three distinct structures involved in the instigation of a myoelectric signal (161):

1) The pre-synaptic terminal;
2) The synaptic cleft, and
3) The post-synaptic membrane.

The pre-synaptic terminal lies at the end of the motor neuron, and contains vesicles which house Acetylcholine, a neurotransmitter. When an action potential is received at the pre-synaptic terminal, calcium gateways within the pre-synaptic terminal are opened and Calcium ions are able to enter into the pre-synaptic terminal. These calcium ions release acetylcholine from vesicles within the pre-synaptic terminal which enter the synaptic cleft, which is the area between the nerve fibre and the muscle's post-synaptic membrane within the motor end plate. The acetylcholine binds to receptor within the post-synaptic membrane, opening small channels within the membrane, which specifically allow the passage of (predominantly) sodium ions into the muscle. This rush of positively charged ions effectively depolarises the membrane, causing an electrical signal to be discharged, which is transmitted along the length of the muscle sarcolemma. It is the summation of these numerous myofibril discharges that is termed the myoelectric signal (158, 160, 161).

Acetylcholine is broken down into acetic acid and choline by the enzyme acetyl cholinesterase, which prevents excessive ionic movement through the membrane and limits the time during which a signal may be transmitted (normally around 10 milliseconds). (160) The sodium-potassium pump will help to restore the balance of these ions across the membrane, thereby also restoring its resting potential and preparing it potentially for further activation (160, 161).

Each muscle fibre will produce a distinct signal, termed a motor unit action potential (MUAP) (158). Each MUAP will contribute to the overall myoelectric signal strength. Where more muscle fibres are present, the signal will inherently be larger, as a summation of the individual signal strengths. However, the wave-like nature of the signal will mean that the amplitude, or effective signal strength, will be affected by amplitude cancellations that occur when the MUAP's superimpose during muscular contraction (165).

The signal strength at the skin's surface will not only be affected by the muscle fibres. Before the signal reaches the skin, it must travel through other layers of tissue, which will all affect the signal size before it reaches the surface (158). The following section outlines the changes that occur during this passage.

2.13.5 *Signal dissipation between the muscle and the skin's surface*

The amount of signal produced within each muscle for different individuals will vary significantly, due to the variations in muscle contraction and signal impedance between the signal source and the electrode interface. In addition, some potential prosthesis users are not as proficient at producing the required myoelectric signal (160).

Other factors that will affect signal clarity and magnitude at the skin surface include the following:

- The composition of the layers of tissue (i.e. the tissue thickness and type) between the electrode and the 'target' muscle producing the required myoelectric signal (158, 159, 163, 164, 166);
- The alignment of the muscle fibres with respect to the alignment of the electrode (167-171);
- The activities of other muscles within the residual limb when the target muscle is contracted (158, 167-171).

The acquisition of an adequate myoelectric signal is influenced by the summative effect of the muscle fibres that are in the locality of the electrode surface, and the amount of impedance to the signal between the fibres and the skins surface (163, 164, 166). Other tissues that exist between the muscle belly and the skin, such as subcutaneous fat, will reduce

the signal strength as it travels to the surface (163, 164, 166). The thickness of the subcutaneous fat affects not only the signal amplitude itself, but will also increase cross talk between the muscle groups that are contracting, distorting the signal clarity and making false signal acquisition and poor control more likely (163, 164, 166).

The activities of muscles other than the specific 'target' muscle pose particular problems for myoelectric prosthesis usage. The use of myoplasty, creating antagonistic pairs of muscles, plus the existence of many small muscles within a residual limb (particularly relevant in transradial residual limbs, see **tables 2.1 & 2.2**) mean that individual myoelectric signals may be produced from multiple sources (94-96). These multiple signals can potentially interfere with signal acquisition from the 'target' muscle, a phenomenon known as cross talk (39, 40, 157-160, 174, 175)**.** Surface electrodes acquire signals at relatively large distances between the signal source and point of acquisition (unlike internal needle electrodes), meaning that multiple sources will be acquired, albeit at varying signal strengths (157-160).

The major tissue layer that affects the acquisition of the myoelectric signal is the outer layer of the epidermis, namely the stratum corneum (157, 158, 170). Variations within this structure and the layers of dead cells and other material that exist over the muscle belly will also affect the myoelectric signal acquisition (157, 158, 170).

Damage to the skin or loss of tissue due to trauma or burns, plus surface hair may also affect the impedance of the myoelectric signal. The influence of skin surface factors may be reduced with the use of electrolytic gel or metallic paste, which is commonly applied to the appropriate part of the skin prior to Electrocardiogram measurements (170, 173). The use of alcohol-based lotions is also commonly employed, although not found to be as effective (170, 173). In addition, the area being used to acquire a myoelectric signal is often shaved prior to the application of the electrodes. All of these preparations will reduce the impedance of the skin, which is responsible for the dissipation and reduction of the myoelectric signal (170, 173).

2.14 *Myoelectric signal acquisition*

Clear acquisition of the myoelectric signal is the fundamental element required for effective myoelectric prosthesis control and operability (39, 40, 174-183). The interface

between the prosthesis and the residual limb is an area where biological tissue meets a technological material and componentry (39). An intimate interface will inevitably lead to a stronger link between the prosthesis and its user, resulting in a more functional and usable prosthesis (34, 35, 40, 121, 182).

The myoelectric signal is relatively small in terms of its voltage, particularly when it reaches the surface of the skin. This would not provide problems if it were to be acquired with respect to a background voltage of zero. However, this is not the case. The human body acts as a natural 'antenna', attracting many small voltages that exist within the environment; as a consequence, the human body has a natural resting voltage of around 6 volts (39, 40, 184). This naturally occurring voltage is termed the common mode voltage (39, 40, 184). The common mode voltage is of course much higher than the myoelectric signal value and hence would dwarf any myoelectric signal that was produced if this was acquired and measured against a common zero-voltage baseline. Consequently, myoelectric signal recognition and usage would be almost impossible if the common mode voltage was also an active signal (39, 40).

For the myoelectric signal to be usable, the electrode used should be able to accurately measure the myoelectric signal voltage and be able to distinguish this from the much larger common mode voltage (39, 40). These factors led to the use of differential electrodes in myoelectric prostheses. They have the advantage of being able to select the myoelectric signal as the source, and are able to filter out the common mode voltage (39, 184).

2.14.1 *Differential electrodes*

Differential electrodes effectively eliminate any constant voltage that is acquired, only recording additional voltages as 'live' signals (39, 40). This meets the myoelectric signal acquisition requirements at the surface of the skin; the common mode voltage is the background signal requiring filtering, the additional voltage is the myoelectric signal requiring recognition and amplification.

Signal acquisition is therefore provided by differential electrodes, which filter out the common mode voltage by creating a new 'base line' at the common mode value, and are then able to record additional myoelectric signals with respect to this. The standard differential

electrode used in signal acquisition for myoelectric prostheses is a bipolar electrode (158, 181, 185, 187-189). This consists of 3 separate electrode contacts; a reference or baseline contact, a negative contact and a positive contact. The negative and positive contacts will register additional signals above the common mode voltage at opposite polarities i.e. positive and negative, with the difference between the two values being amplified. Effectively, therefore, the myoelectric signal is doubled prior to amplification (40).

2.14.2 *Signal amplification*

The amount of amplification which occurs in most clinically available myoelectric systems can be adjusted by the Prosthetist to suit the individual requirements of each potential prosthesis user (72). Achieving the required signal strength is essential if effective myoelectric control is to be realised (39, 40, 185, 189). The minimum signal strength normally required is 15 micro-volts, but for a two-site system i.e. one that uses 2 electrodes on separate muscle bellies, ideally there should also be a differential of at least 5 micro-volts between the electrode contacts for a dominant signal to be recognised (39, 40). In many cases, one muscle group predominates, and since the muscles work as antagonistic pairs i.e. contract in opposition under both wrist flexion and extension in transradial residual limbs, this may cause one signal to be dominant and make it difficult for the user to perform the function of the prehensor or electrically-powered component associated with the electrode acquiring the weaker signal (39).

To compensate for signal imbalances between antagonistic muscles, most electrodes have an adjustable amplification or ‘gain’ feature, usually taking the form of a numbered dial on the outer surface of the electrode (159, 185). The Prosthetist may alter the amount of amplification independently on each electrode by setting the dial onto the required amplification value using with either a specifically manufactured adjustment tool or a small screwdriver. Consequently, should an imbalance exits between the signal acquisitions at two different sites, one site may have the electrode amplification increased (the weaker signal) whilst the other may be decreased (the stronger signal) until a balance may be afforded between the two sites that enables the prosthesis user to acquire the necessary level of control (39, 40).

The variances that exist between prosthesis users in terms of signal generation and acquisition often results in relevant variances of prosthesis controllability. Some users can

systematically reach a target myoelectric signal threshold of 15 micro-volts but cannot control the size of this signal beyond this, while others have a good deal more control over the signal strength that is produced (72, 73). For this reason, there are different types of control system offered to myoelectric prosthesis users, depending on the level and repeatability of the signal that they are able to produce (39, 40, 72, 73, 80).

2.14.3 *Myoelectric signal processing*

The myoelectric signal must be processed appropriately before it is ready for use as an operative method of prosthesis control. The original signal is alternating, roughened and sporadic with a mean value of zero (40). It must be rectified and smoothed (using an arrangement similar in principle to a simple Wheatstone bridge) before it is suitable for prosthesis activation (40).

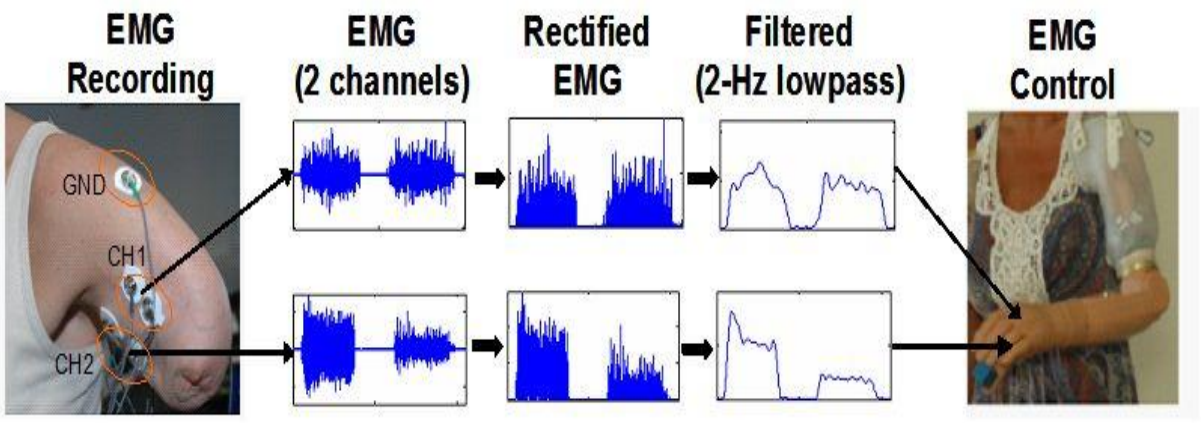


Figure 2.7: Raw (AC) biceps myoelectric signal, rectified (DC) myoelectric signal and smoothed (normalised/filtered) myoelectric signal (190)

In essence, the numerous 'spikes' created by the multiple myofibrils contributing to the overall signal must be collated into one measurable value (40, 190). In addition, this must be a measurable value, not an overall zero value as it originally presents, if it is to be used as an effective operative signal. The rectification process achieves this, in simple terms, by effectively folding the signal graph as it would first appear (see **figure 2.7**) along the x-axis (zero) and placing what was the negative value over the positive value, or vice versa (40). This has the effect of removing the negative part of the signal, and thereby leaving a positive value that may be used to operate a myoelectric prehensor (190). Signal filtering, also evident within **figure 2.7**, will be examined in section 2.16.4.

The myoelectric signal itself will vary whilst the muscle undergoes contraction; ideally, the greater the degree of voluntary contraction, the greater the recorded value of the myoelectric signal (39). To a certain degree, this proportional relationship between muscle contraction strength and signal value does occur naturally, with the myoelectric signal being seen to increase as a force function in relation to the muscle contraction that occurs (166, 191-193). However, this is not always the case. Muscle fatigue, along with the natural variance of the myofibril discharge, can potentially vary the signal, and provide a disproportionate response for the prosthesis user in terms of effort and activation (158, 191)

2.15 *Types of myoelectric control*

The simplest form of myoelectric control is called threshold control, which relies on the acquisition of a 15 micro-volt signal to perform a single operation, such as hand opening or closing (40, 72). This operation remains the same, i.e. the hand opens or closes at the same rate or with the same grip strength, regardless of the size of the signal. As long as the signal is above the threshold value, the response of the component will not alter. Although this is the simplest type of control to learn, and therefore the most easily implemented by prosthesis users, it offers limited prosthesis functionality (72). There is no feedback during usage, with the prosthesis user not able to correlate larger input contractions with increased prehensor responses (40, 72).

This usability in increased by the incorporation of a more intricate control system, called proportional control within a myoelectric prosthesis (40, 72). Proportional control also relies on the acquisition of signal of at least 15 micro-volts threshold, but as the acquired signal strength increases beyond this threshold, so the prosthesis component reacts proportionally to this increase, either by moving faster or attaining greater levels of grip strength. The range of applications that may be provided by a prosthesis incorporating the proportional control system is obviously much greater, but conversely it requires the prosthesis user to have much better control of their own myoelectric signal. Unfortunately, this is not often the case, meaning that the benefits of proportional control are not actually realised (194, 195).

2.16 *Myoelectric control strategies*

The strategy for controlling the myoelectric device, usually a hand, is designated by the number of electrodes, or *sites*, that are employed within the system, and the number of

functions, or *states*, that are available for control and activation purposes. Depending on the users' requirements and signal generation capabilities, the site-state system will vary to match both these aspects and the prosthesis components that are employed (40).

2.16.1 *Two-site / two-state control*

The two-site / two state control strategy is the most common control strategy in clinical usage (40, 175, 194, 195). It employs two electrodes located on specific sites over the target muscles. The standard arrangements for the two electrode locations are:

- One electrode is placed over the 'flexor' muscle group which controls the hand closing function;
- The other electrode placed is sited over the 'extensor' muscle group which controls the hand opening function.

Accordingly, a two-site two-state strategy has two electrodes positioned over the residual limb muscle groups, each one performing one function. If the appropriate muscle is contracted, and the signal reaches the threshold required, then this function is performed. However, the residual limb muscle groups work in antagonistic pairs, meaning that a contracting target muscle group, i.e. the flexors, will naturally induce contraction within the opposing muscle group, i.e. the extensors. If both signals are of similar strength (with a difference of <5 micro-volts) hand operation may not occur, even if the signals are above the signal threshold (39, 40, 70). The Prosthetist will be required to adjust the signal amplification on each electrode to provide effective control from each site (176). However, in some systems, co-contraction of two muscle sites can be used as a switch to change the target device, i.e. from a myoelectric hand to an electrically-powered wrist (70, 72). Regular usage of the electrode sites then activates the wrist, not the hand, until co-contraction is performed again, and the switch resets the target device as the hand.

In a threshold controlled system, the hand will open or close at a fixed rate, regardless of how large the myoelectric signal is. In a proportional controlled system, the hand will open or close, and provide grip strengths, which are proportional to the size of the signal that is acquired. The former system is more widely used, as it easier to employ and does not require

the user to have the same high-level of signal control that is need for proportional control (40).

2.16.2 *Two-site / four-state control*

The two-site / four-state control strategy again employs two electrodes, but each site also has an extra function, normally the control of either a wrist or elbow unit (72). In this strategy, the co-contraction of muscle groups is actually used as part of the control system. When the muscle groups are actively co-contracted, the control is switched from the hand to the either the wrist or the elbow unit. Signal activation then results in wrist rotation or elbow flexion / extension. Further co-contraction switches the control back to the hand.

2.16.3 *Single site control strategies*

Where there is insufficient muscle tissue or control to operate two electrodes, single site control strategies may be used (73). Children are initially prescribed single site control systems, which normally induce hand opening from the single site, with automatic hand closing once the signal is removed (73). This strategy is called one-site, two-state control.

Other single site strategies include one-site, three-state control. This strategy separates the active range of the processed myoelectric signal into 3 regions: rest, close and open, with two distinct signal thresholds (196). Under the lower signal threshold, the system is at rest. Between the lower and upper signal thresholds, the hand will close. Above the upper signal threshold, the hand will open.

Both one-site, three-state and two-site, two-state control strategies require the prosthesis user to have optimal control of their target muscle group(s) to achieve successful functional outcomes.

2.16.4 S*ignal filtering and electrical 'noise'*

Effective myoelectric prosthesis operation is dependent on acquiring a clear, recognisable myoelectric signal, which is easily interpreted by the processing system as the operative signal (39, 40, 158, 159, 184, 197-204). Unfortunately, signal clarity is often inhibited by electrical 'noise' which can interfere with and sometimes mask the myoelectric signal, making it difficult to acquire efficiently (40, 205). There are two main types of noise that can affect myoelectric signal acquisition:

1) Ambient noise: this refers to the electrical emissions of electromagnetic devices, such as power lines, fluorescent lights and household appliances (40, 205). Any electrical item that runs off an alternating voltage will emit ambient noise. Most clinically used myoelectric systems, such as the standard RSL Steeper myoelectric control system which will be used within **chapters 5 & 6**, provide notch filters at specific frequencies, such as 50-60Hz, which are within the myoelectric signal spectrum but which also correspond to the standard power output frequencies in the United Kingdom (69, 177, 198). The notch filter will remove frequencies within this very narrow frequency range. However, filtering these frequencies can also remove a significant part of the myoelectric signal (40, 205). Ambient noise can be potentially disruptive to myoelectric signal acquisition, particularly as the signal, and hence any interference, is amplified at its source (40).

The myoelectric signal will present at the skin's surface within a specific frequency range, normally between 0 and 500Hz (69). In addition to the myoelectric signal, other signals with varying frequencies may also be acquired from surrounding electrical and electronic devices. To prevent these and other signal sources from interfering with the myoelectric signal, filtering techniques are used to try to eliminate external signals whose frequencies lie outside of the range of the myoelectric signal (69, 177, 198, 205). The types of filters employed have been recommended by the European community project on surface electromyography, SENIAM (170). Low pass filters (see also **figure 2.7**) are used to remove high frequency signals (SENIAM recommends signals >500Hz) (170), and high pass filters are used to remove low frequency signals (SENIAM recommends signals <10-20Hz) (170).

2) Transducer noise: this refers to the noise that is present as a result of chemical reactions that occur at the interface of the electrode and the skin, and the changes in impedance that result from these (178, 186, 205, 206). The electrode must convert what is essentially an ionic electrical signal within the muscle into a digital readable signal which can be processed and stored as a voltage potential (40). This conversion process makes the interface between the electrode and the skin extremely important in terms of prosthesis control and is potentially prone to signal disruption if the electrode-skin interface environment is not stable (10, 31, 39, 40, 151, 163, 167-173, 176, 177, 188, 194, 198, 200, 201, 205).

Effective signal acquisition and an efficient system of operation is dependent on a high target signal-to-noise ratio (40, 205). The greater this ratio is, the better the signal clarity

and the more effective the signal processing and usability (39, 40, 69, 177, 198, 205). Improvements in electrode technology, such as the introduction of bipolar electrodes, have improved the ability to acquire a clean and usable signal. However, simple skin preparation techniques, including cleaning and using electrolytic gel, can have even greater effects, improving noise reduction by up to 10 times (158, 159). Skin preparation is recommended by the SENIAM European project as part of the best practice for standard EMG signal acquisition, but is not standard practice for myoelectric prosthesis signal acquisition (170).

Noise is not the only factor that can inhibit the signal acquisition process; if the electrode is not physically stable then this could lead the production of false signals or motion artifacts which will interfere with the myoelectric prosthesis control and operation (39, 40, 205).

2.17 *Motion artefacts and prehensor control*

The role of the differential electrodes is to filter the common mode voltage and to acquire and amplify the myoelectric target signal from the muscle bellies over which they are positioned. However, if the individual electrode is not securely fastened to the skin, relative movement at the electrode/skin interface can lead to the production of motion artifacts (39, 40, 177, 194, 207). These can occur in two ways:

1) Electrode slippage: This occurs when the electrode is allowed to move across the surface of the skin whilst still remaining in full contact with it. The charge differential, between the skin's surface and the electrode surface create what are effectively two charged plates of a capacitor (40, 177). When these plates move relative to one another, an electrical discharge is emitted. This discharge may then be acquired by the electrode and hence lead to the false activation of the myoelectric prosthesis component (39, 40, 207).

2) Electrode lift: This occurs when all or part of the electrode temporarily becomes detached from the surface of the skin (39, 40, 177, 194). When this occurs, the common mode voltage may become an active signal before the new baseline is stabilised. In addition, if only one of the contacts is detached from the surface of the skin, the common mode voltage is obviously not acquired at all of the contact points and hence will effectively be an active signal (39, 40, 177, 194). This will then lead to activation and potentially false operation of the myoelectric prosthesis. Anecdotal evidence actually suggests however that some myoelectric prosthesis

users manipulate their residual limbs within the prosthetic socket, deliberately separating the skin's surface from the electrodes in order to provide the desired prosthesis response, much like a switch. This potential usability from what is generally recognised as a hindrance to prosthesis usage is open to further analysis and investigation.

Clearly, the manner in which the electrode is secured to the skin will influence signal acquisition and the potential occurrence of motion artefacts from the two sources listed above. Despite the specific requirements stated above for electrode positioning and stability, this process during prosthesis assessment is still very much 'trial and error' with regard to finding the most suitable electrode site.

2.18 *Improvements to signal acquisition*

Achieving a strong, 'cleaner' myoelectric signal, free from noise disruption and cross-talk, is clearly advantageous for effective myoelectric prosthesis usage. Current methods used to improve acquisition of the myoelectric signal involve improving either system processing or interface security.

2.18.1 *Improvements to system processing*

One method of improving signal recognition is to provide systems that only respond to the unique myoelectric patterns of the target muscles firing in sequence; these systems are known as 'pattern recognition systems'. By reacting only to specific muscle patterns, cross-talk from other muscles is potentially negated. Various authors have promoted such systems, although the research data has often been collated with regard to the natural arm (not the residual limb of a prosthesis user) (208-210). Myoelectric signals are generally easier to acquire and control using muscles within the sound forearm, rather than those within the residual limb, as visual feedback is available from the natural wrist movement. In addition, muscles within the natural forearm are more clearly defined, and are unlikely to have been repositioned due to either surgery or limb deformity.

Clearly, the target muscle pattern must be precisely located by the Prosthetist for successful signal recognition to occur. Problems may occur with regard to muscle location and definition within the residual limb, making these difficult to recognise and identify, particularly if the Prosthetist is relatively inexperienced with regard to the provision of myoelectric prostheses. In summary, although pattern recognition theoretically provides a

clearer signal, practical clinical difficulties with respect to muscle recognition and clinical viability provide barriers to the uptake of this system within standard clinically-available prosthetic hands.

2.18.2 *Improvements to electrode interface security*

Improving socket security has already been discussed and since electrode housings are securely fixed within the socket walls, these influences will also naturally affect the electrode interface security. Suction sockets are to some extent employed within upper limb myoelectric prostheses (22, 211). They are donned using a pull-through sock that covers the residual limb prior to donning, with the end of the sock prominent prior to application of the socket. This prominent sock end is literally pulled through the socket and the forearm via a tube section, which connects the distal end of the socket with the exterior of the forearm. However, suction application is by no means applicable for all patient types and relies on a stable limb volume and a relatively soft residual limb with no potentially sensitive areas (132). Application of the socket with regard to its position over the residual limb may not always be consistent, meaning that the electrodes may not always be in the optimal site for signal acquisition (211).

A number of studies have employed the use of roll-on sockets in tandem with myoelectric control and operation (212). An early example of this was demonstrated by Salam (1994), who placed the electrodes in the desired optimum signal positions on transhumeral residual limbs within cut out sections of the roll-on sockets (135). The prosthesis results appeared to be successful; however, making cuts within the roll-on sockets is not ideal, as anecdotal evidence suggest that this can lead to the sockets becoming ripped with continuous usage.

A more viable long term option has been provided by the availability of snap-fit electrodes, manufactured within roll-on sockets. These are specifically designed for myoelectric prosthesis provision and therefore the roll-on sockets are not mechanically weakened by the inclusion of the electrodes. Studies by Daly et al (2000) and Gaber et al (2001) have shown clear advantages with regard to the usage of these systems (33, 34). However, the general disadvantages of roll-on sockets, such as sweating, socket shape and contouring with respect to the residual limb, and donning and doffing the roll-on socket, remain (213).

The options available for upper limb functional prosthetic replacement are therefore many and varied, but each one has a common goal; which is to replace as much upper limb functionality, or functional usefulness, as possible for the prosthesis user. However, there is clearly a need to establish and assess the specific functional and prehensor control restrictions caused by improper electrode contact in conjunction with the movement that is afforded by current upper limb prosthesis socket types.

2.19 *Chapter summary*

The natural upper is hugely complex, sophisticated and capable. Its dual requirements of cosmesis and function make prosthesis replacement very challenging, as effective functional devices are not necessarily cosmetic. The residual limb that remains following amputation, or exists following birth, will include the remnants of muscles that may be contracted consciously. However, controlling these muscles is inherently challenging for most individuals.

There are a number of prostheses and components that may be used for upper limb absence, each one relying on very different methods and applications to replace functionality and to meet user requirements. There are also variations and modifications available for the sockets that form the interface between the natural residual limb and the prosthesis itself, although importantly most of the key features for each socket type are applied similarly for prostheses of different types at each level.

Myoelectric prostheses offer the most realistic potential for advancing the quality of prosthesis replacement, but acquiring the myoelectric signal is potentially problematic, including numerous factors that are inherently changeable. The implementation of myoelectric control has not been as successful as many had predicted. By the mid-1980s, serious questions were being raised regarding the future of myoelectric signal acquisition as a suitable control mechanism for upper limb prostheses (11). In particular, problems with control of the hand and/or wrist unit were still frequently noted, and many users appeared to be rejecting myoelectric prostheses in favour of either body-powered or cosmetic prostheses (6).

Socket design has not altered significantly for the large majority of sockets that are currently employed within upper limb prostheses. Many sockets currently employed may

allow movement to occur and disrupt the signal source, and also allow false signals to occur in the form of motion artefacts. These could be hampering the usability of the prosthesis and stifling usage rates and levels of prosthesis functionality.

Socket movement with respect to the residual limb has clearly been recognised as potential problem in standard socket designs, with the largest change in socket principles being introduced via the total surface bearing concept of the roll-on socket. Although this socket is now extensively employed within lower limb prostheses, in many cases to provide comfort for the user on weight bearing, its initial conception was derived from the need to reduce relative movement between the socket and the residual limb.

Improvements in socket design, such as the roll-on socket, have increased the security of the fit between the residual limb and the prosthesis (113). As a result, these have been used with electrodes incorporated within their structure on myoelectric prosthesis. Prostheses incorporating roll-on sockets appear to show increased levels of functionality when compared to standard electrode arrangements, which may be as a result of the increased security between the electrode and the surface of the skin (33, 34, 35, 212). However, donning and doffing the sleeves accurately and maintaining the electrodes over the correct sites at all times may be difficult for prosthesis users to achieve, particularly when they have only one functioning arm. This is also true for suction socket fitting. In addition, increased sweating caused by the intimate fit of these sockets may also contribute to the functional improvements that have been noted, due to the subsequent reduction in skin impedance (33-35). Further studies are required to establish the absolute contributions of the factors involved if the functionality of myoelectric prostheses is to be permanently improved.

This reduction in movement has led to the introduction of electrodes within roll-on sockets, the reduction in movement clearly recognised as an important factor in prosthesis functionality. However, the extent to which the improved socket security impacts on increased functionality is not specifically recognised. Other factors, such as increased sweating and the reduction of impedance to the myoelectric signal, may also affect signal acquisition. In addition, the roll-on socket is not a viable option for a large number of prosthesis users, because it is difficult to don and doff, and requires good cognitive capabilities (213).

The myoelectric control system relies on a number of key elements, which must all working effectively to deliver the appropriate hand or prehensor responses. If this responsiveness is compromised by one element, such as the electrode to skin contact, then the whole system will be equally compromised, regardless of how much the other elements, such as the hands, may be technically improved.

The perceived intimacy of the contact between the myoelectric electrode surface and the skin within a socket designed for myoelectric control in transradial amputees may be crucial in defining prosthesis functionality. However, this interaction has not been extensively investigated in the literature, and is one of the key outcome measures for this thesis. This thesis also investigates levels of prosthesis usage and the types of activities for which transradial prostheses are employed, and examines and contrasts the results with previous studies that have been conducted within this area.

Clearly, it is important to determine the impact that the socket design and the efficacy of the electrode contact at the skin interface may have on the levels of functionality and usability afforded by myoelectric prostheses, and to what extent specific activities incur socket related problems. Although movement is evident, where and when this movement occurs, and during which activities and under which conditions, is not clearly understood. To this end, the next chapter investigates prosthesis user responses to questions relating to perceived socket and electrode tightness and correlates and contrasts these responses with the resultant reliability of the myoelectric hand or prehensor.

Chapter 3:
Analysing the relationship between socket fit, electrode contact and myoelectric prosthesis usage and prehensor response: a prosthesis user questionnaire

3.1 *Introduction*

The design objective of any prosthetic device is to be fit for purpose, and to meet the requirements of its user as well as providing appropriate function. Therefore, acquiring accurate user feedback is clearly an essential part of the design process. An upper limb prosthetic device can play a significant and intimate role in a person's daily activities and lifestyle. Findings from users' perceptions of prosthesis performance and functionality using appropriate assessments should influence future prosthesis designs and componentry, thereby having the potential to impact significantly on prosthesis user comfort, confidence and potentially their quality of life. It is therefore essential that these investigations are implemented to truly reflect user' views and opinions.

The analysis of upper limb prosthesis functionality is inherently complex. This is because the functional requirements that upper limb prostheses need to provide are wide-ranging as they attempt to replicate and emulate some of the basic functions provided by the anatomical upper limb. The functions, uses and capabilities of the natural upper limb are extremely diverse, and therefore applying a suitable blend of features from such a wide range of options to prosthesis design is complex and challenging for the prosthesis designer. Each prosthesis user will normally have distinct and often quite diverse opinions on what they would like to achieve when wearing their upper limb prosthesis; so further complicating the design process, and there is evidence of high levels of abandonment of upper limb prostheses. It is for these reasons that most user assessments have focused primarily on relatively simple, generic functions and features of upper limb prostheses which can be easily and simply replicated, recorded and contrasted (6).

Other factors have influenced previous user assessment techniques such as interviews, surveys or questionnaires and the ability to obtain a large enough pool of data concerning upper limb prosthesis use. There are relatively small numbers of upper limb prosthesis users compared to lower limb prosthesis users, and therefore acquiring suitably large 'pools' of recipients for surveys is difficult. Additionally, these user numbers are further diminished by the apparently large number of potential upper limb prosthesis users who do not wear any

prosthesis type (6, 48, 52, 53). These individuals' views are just as essential to the researcher, since their reasons for prosthesis rejection clearly have important design implications for future upper limb prostheses (120, 214).

A number of generic surveys have been published, which generally intimate that myoelectric prosthesis usage is not as prevalent as may have been expected, given the appeal of bionic sophistication, and the fact that traditional designs such as the body-powered split-hook have changed little over the last 100 years (6). However, surveys dedicated specifically to functional myoelectric prosthesis usage and control, particularly those that examine functional response and its effect on the uptake and long-term usage, are rare. Despite this apparent lack of user feedback, myoelectric prosthesis design is continuing apace; the development of multifunctional hands, improved processor control systems and device actuators are just a few of the technical improvements that have been highlighted over recent years (215-218). However, without the representative user feedback and the sustainability of prosthesis control, questions will still remain as to whether these introductions will actually provide the improvements that will benefit daily usage.

There is little available evidence that suggests that any theoretical loss of contact between the electrode and skin during myoelectric prosthesis usage actually leads to a loss of functionality, which will in turn lead to rejection of the prosthesis. Myoelectric prostheses provide the user with a combination of function and cosmesis; and consequently, functional impairment caused by loss of electrode contact may not be a priority for some users. However, the impact on prosthesis functionality of the socket and electrode contacts in terms of their perceived tightness and security over the residual limb has remained largely unknown. Despite the perception that these socket features are inherently essential for optimal usage, no clear evidence of a direct link between prosthesis usage and socket fit exists. The effect of socket shape, local security over the electrode housing and more recent changes to myoelectric systems to filter out unwanted signals may all contribute to the levels of prehensor control that are actually afforded to the user. In addition, anecdotal evidence suggests that some users may employ their myoelectric contacts as switches and employ loose sockets to enable them to use the resulting motion artifacts to actually control their prostheses, rather than the prescribed myoelectric signal control.

This chapter therefore focuses on an investigation of the implications of myoelectric prosthesis reliability and consequent functionality, with specific regard to prosthesis users' estimation of the tightness of the fit of both the socket and the electrode and its potential effect on the functional reliability of the myoelectric hand. To enable this data to be collected, a specifically designed questionnaire was developed. The following section outlines a review of the evidence in the literature regarding previous questionnaires developed specifically for upper limb prosthetics, describes the drivers for development of the questionnaire used in this study, and the reasoning behind its structure and content.

3.2 *Previous upper limb prosthesis usage investigations*

Upper limb prosthesis usage has previously been investigated using single subject analysis, functionality assessments or surveys and questionnaires. Each type of assessment provides potentially useful data if it is integrated effectively with data from the other types, since no single assessment can as yet perform an ideal examination of prosthesis capabilities and users wishes and requirements.

Assessments that examine specific device characteristics are mostly employed by engineers or those seeking to enhance technical features of either new or existing devices (141). By contrast, functionality assessments, and sometimes questionnaires, are usually performed by therapists, most notably Occupational therapists involved with upper limb prosthesis rehabilitation (86, 87). Surveys involving the prosthetic socket are rare; these would normally be carried out by Prosthetists, and it is this area which will be examined later within this chapter.

The following sections examine the results that have been acquired so far from the three forms of assessment that have been highlighted.

3.2.1 *Comparative assessments and device-based investigations*

Historically, prosthesis assessments involving myoelectric prehensors have often been technically orientated. Newly-developed or re-designed myoelectric prehensors have often been compared with the body-powered split-hook type in studies when analysing simple and specific activities (6). Viewing the split-hook as the 'gold standard' in terms functional usability is questionable however, since this is not a modern device (it has been available for over a century) and can no way be considered to be as usable as the natural hand (57). In

similar assessments, using a split hook has been found to take twice as long as the same task undertaken with the natural hand (126). However, using a myoelectric prosthesis was said to take more than twice as long as the split-hook itself (126).

Most prehensor-based evaluations involve the use of only one subject (6). An early example of this form of study was carried out by Agnew (1981) who found the split-hook to be more functionally useful than a myoelectric hand (219). The assessment methods used at this time were based around simple timed tests, which although easy to measure, may not provide the most accurate levels of functionality measurement.

Another example of single-subject study was conducted by Meredith (1994), who compared the relative capabilities of a split-hook, a myoelectric prehensor and an electrically-powered hook using a single-subject prosthesis user (88). A series of ADLs and standardised measures were used in this investigation, although it was said that some familiarity with the equipment may have influenced the results. In this study, the results indicated that the electrically-powered hook was the most functional prehensor, although the user was said to be most familiar with this device, which possibly skewed the results (88).

Carey et al (2009) also used a single subject study to compare the functional usability of a body-powered split-hook to that of a modern myoelectric hand prehensor, again using ADLs based on common daily tasks (19). The body-powered prosthesis was employed for more common tasks but the prosthesis user was said to be reasonably proficient with both prosthesis types (19).

Investigations contrasting the available function from different methods of operation have also taken place, most notably those examining the respective function available from voluntary opening (VO) split hooks (the standard method) or voluntary closing (VC) split-hooks (6). Crandall and Tomhave (2002) found that the voluntary closing split-hook was the most functionally effective (20). This type of appliance is also used more extensively in upper limb sports prostheses, since the users can regulate the amount of grip strength and hence perform more accurate movements and tasks (220). In standard voluntary closing devices, the grip strength is pre-set, usually via the use of electric bands positioned around the proximal aspect of the hook (4).

The VC hook was found to require less activation force than the VC hand to achieve similar levels of grip strength by Smit and Plettenberg (2010) (138). The grasp dynamics of the split hook, rather than the addition of a cosmetic glove, was said to have been the cause for this significant (8 times larger) difference in required mechanical exertion (138).

A small number of studies have also compared myoelectric prehensors (6). Kyberd et al (2011) used the SHAP to assess the functionality of a range of myoelectric hands, with differing operating options (141). These options included different control methods, such as threshold and proportional, as well as different opening regimes, such as VO and VC, and differences in the degrees of freedom afforded by each hand. Of all these factors, it was the control method that proved to be the most influential, although the single subject was not a prosthesis user (the signal acquisition was attained from the author's forearm for this paper) (141).

Van der Niet et al (2010) compared the respective functionality attained from the I-Limb (a multifunctional, multiple degree of freedom myoelectric hand) with a single degree of freedom, more standard myoelectric hand, the Otto Bock DMC (8). The assessment methodology again included the use of the SHAP, with the subject this time being a prosthesis user, at the wrist disarticulation level of limb absence. The i-limb proved to be no more functional overall then the Otto Bock DMC, and had an overall functionality index score (74/100) that was significantly higher than the I-Limb (52/100) (10). However, the prosthesis user stated that they preferred the I-Limb, despite the greater degree of functionality that was apparently available from the Otto Bock DMC (8).

These comparative studies offered an accurate representation of an individual's distinct functional capabilities, and could be quantified and repeated consistently, but had a very narrow scope of application, and often did not relate to overall prosthesis functionality. The small numbers of subjects involved in these types of studies, who were not always prosthesis users, limits the effectiveness of the data in achieving overall prosthesis goals as defined by prosthesis users.

Larger scale studies of upper limb prosthesis usage patterns have been undertaken, and have normally employed the use of questionnaires. The following section outlines the results and implications of some of these studies.

3.2.2 *Upper limb prosthesis usage patterns and survey results*

Questionnaires have been widely used to acquire prosthesis functional usage rates from larger numbers of users and also have the advantage of being genuinely equitable in sourcing information (57, 80). In addition, they may be distributed to larger numbers of upper limb prosthesis users than would reasonably be expected to participate in other functionality assessments (80).

Surveys in various International countries, with different prescription availability for myoelectric prostheses, have generally demonstrated relatively low uptakes and usage rates for myoelectric prostheses, although the focus of these assessments has not specifically targeted functional capability or specific levels of myoelectric prosthesis usage (14-18, 20, 21, 49).

Body-powered prostheses have been shown to be worn for longer periods than myoelectric prostheses by the majority of upper limb prosthesis users for work-related activities (6). Stein and Whalley (1983) demonstrated that a prosthesis user took twice as long to undertake similar tasks with a body-powered prosthesis, and five times as long with a myoelectric prosthesis, when compared to a fully-functioning natural hand performing the same tasks in one study (126).

In 1989, Roeschlein and Domholdtz surveyed 86 prosthesis user subjects in Indianapolis, USA (221). Most of those surveyed wore body-powered hooks for functional purposes; these were deemed functionally useful by the majority (65%) of those surveyed. Very few users (only 3) used myoelectric prostheses, and only 1 of these users deemed their prosthesis functionally useful (221).

At around the same time, Balance and Wilson (1989) in Canada found that new sockets were being refitted to approximately 30% of the prostheses worn by children within their survey (51). Socket design and delayed response times were quoted as disadvantages with respect to the myoelectric prosthesis, which was only worn part of the time during the day by those supplied with it (51). **Table 3.1** (below) provides an analysis of the studies published to date which have investigated upper limb prosthesis using case studies, functionality assessments or questionnaires.

Author	Study type	Ref No.	Sample Size (n)	Level / Prostheses types studied	Uptake %
Stein & Walley (1983)	Review	(126)	20	All levels / All types	-
Van Lunteren et al (1983)	Survey	(18)	13	All levels / All types	61
Millstein et al (1986)	Survey	(147)	83	All levels / All types	33
Glynn & Hunter (1986)	Survey	(93)	78	All levels / All types	86
Datta & Ibbotson (1998)	Review Survey	(222)	29	All levels / All types	-
Balance & Wilson (1989)	Review	(51)	17	All levels / All types	-
Roeschlein & Domholdt (1989)	Survey	(221)	86	Transradial/ All types	56
Jones & Davidson (1995)	Survey	(49)	76	All levels / All types	52
Atkins et al (1996)	Survey	(14)	~2,500	All levels / All types	32
Hubbard et al (1997)	Survey	(235)	142	All levels / All types	45
Kyberd et al (1998)	Survey	(17)	68	All levels / All types	79
Routhier et al (2001)	Survey	(223)	18	All levels / All types	56
Kuyper et al (2001)	Review	(13)	224	All levels / All types (children)	-
Crandall & Tomhave (2002)	Survey	(20)	24	All levels / All types	84
Burger & Marincek (1994)	Survey	(16)	414	All levels / All types	63
Dudkiewicz et al (2004)	Review	(15)	45	All levels / All types	-
Pylatiuk et al (2007)	Online	(12)	54	All levels / Myoelectric	-
Biddiss & Chau (2007b)	Survey	(214)	242	All levels / All types	-

Table 3.1: Surveys performed investigating upper limb prosthesis functionality. A review was an examination of records available within the clinic and not questionnaire-based.

In Slovenia, Burger and Marincek (1994) found that only 2% of users wore a myoelectric prosthesis, with 70% wearing cosmetic prostheses (16). Many amputees within this survey were found to compensate with the natural limb where possible, and most of the

subjects with transhumeral or more proximal levels of limb absence didn't use functional prostheses, which were seen as unreliable. Around this time, in Australia, Jones and Davison (1995) found that no limb wearers were using a myoelectric prosthesis; the body-powered prostheses that were used instead were said to be useful for lifting and carrying activities (49).

The relatively low numbers of upper limb prosthesis users compared to those requiring lower limb prostheses has meant that large scale surveys have been rare. One of the few notable large-scale studies was performed by Atkins et al (1996) in the United States, where the survey sample comprised of approximately 2500 upper limb prosthesis users (14). This survey demonstrated that almost twice as many adult prosthesis users (63%) wore body-powered prostheses compared to myoelectric prostheses (37%) (14). The results demonstrated that multiple functional use was a key priority, as well as the need for enhanced finger movement and wrist function, with less dependence being needed on visual attention during the performance of everyday activities. Myoelectric users also identified electrode reliability in supplying the appropriate signal as being problematic in many cases, and questioned the reliability of both these and the subsequent response of the myoelectric hand (14).

Poor function was quoted as reason for non-usage by Gaine and Smart (1997). Of the 55 users within this survey, the male-female ratio was 8-1 (44). Although daily usage rates were still high, it was said that this is not always a good guide with regard to satisfaction, since there are other reasons (apart for functional employment) for prosthesis usage (44).

Lack of function was found to be the largest problematic factor for prosthesis users who were surveyed in 1998 by Kyberd et al in Oxford, United Kingdom; with almost one third of prosthesis users stating that this was the greatest limitation in the usefulness of their prosthesis (17). Their conclusion was that future functional prostheses should offer more function than current variants, which were also described as being too heavy by many prosthesis users. Cosmetic prostheses could be used for passive functions, but users complained that the wire fingers within the foam hands, which were not devised for functional usage, broke frequently when moved into different positions.

Dudkiewicz et al (2004) surveyed 45 upper limb prosthesis wearers in Israel, but only three of these had previously used a myoelectric prosthesis; all of which were subsequently replaced with a cosmetic prosthesis (15). The cosmetic prosthesis was again the most used of all the prosthesis types. Dissatisfaction issues reported with myoelectric prostheses included increased weight compared with other prostheses, plus the sweating which resulted from an intimately fitting socket and a lack of cosmesis. The average myoelectric limb user was found to be considerably younger than the respective body-powered user. Younger users were said to be more conscious of cosmesis, and favoured a compromise in function for an improvement in prosthetic appearance. At more proximal levels of limb absence, usage of myoelectric prostheses was said to be particularly low.

Pezzin et al (2004) found that upper limb prosthesis users are less satisfied with their prostheses than lower limb users (102). A well-fitting, easy to use prosthesis that enabled the user to undertake ADLs was said to be of paramount importance to the prosthesis user. Datta et al (2004) found that almost 34% rejected their upper limb prosthesis and stated that 'we have no evidence to suggest that the provision of externally powered prostheses for proximal upper limb deficiency are likely to be any more successful in terms of function or lower rejection rates' than other prostheses (21).

However, an internet survey by Pylatiuk et al (2007) demonstrated that a high degree of satisfaction was felt by myoelectric prosthesis users (n=54) of all age ranges with respect to the cosmesis afforded by them (12). Conversely, most myoelectric prosthesis users wanted a higher degree of proprioceptive feedback, which could be more readily accomplished when using a body-powered prosthesis via a harness. Many users complained about the increased weight of the myoelectric prosthesis and the relatively slow grasp speed. This may have been related to electrode sensitivity, because 20% of users also stated that electrode contact and interference issues were a significant problem with respect to the control of the prosthesis (12).

Biddiss and Chau (2007b) found that 20% of those surveyed didn't employ their prosthesis (n=242) (214). Those with acquired limb absence were less likely to reject their prostheses than those with a congenital absence, and more proximal levels were also more likely to reject the prosthesis. Females too were more likely to reject the prosthesis. A large proportion of non-users, 88%, stated that the limb was too tiring and too difficult to use.

These authors stated that ‘future research should focus on more comfortable, functional technology’ (214).

Most surveys conducted between the inception of myoelectric prostheses and the present day still state that body-powered prostheses still have significant appeal, despite the fact that body-powered prostheses do not provide any level of cosmetic appeal, and the harness associated with them is seen as a significant disadvantage for prostheses of this type (4). The performance of finite tasks using all types of prostheses is still found to be problematic, and often leads to rejection (6). Nevertheless, most authors have still concluded that the body-powered prosthesis with a VC split-hook was the most functional type of prosthesis (6).

Of all the user categories, children are the ones most predominantly prescribed myoelectric prostheses (73). The appeal of a ‘bionic limb’, particularly for parents, is hard to resist (6). However, a static socket and a growing residual limb do not appear to be compatible in terms of functional usefulness and are clearly of interest to this thesis. The following section examines those surveys that have been undertaken with children as the prosthesis user subjects.

3.2.3 *Upper limb myoelectric prosthesis usage amongst children*

It has been demonstrated that adult myoelectric users wear their prosthesis for longer periods than children (~8 hours per day for adult prosthesis users, compared to < 4 hours for child prosthesis users) (12).

In the United Kingdom, at Sheffield, Datta and Ibbotson (1998) suggested that the first provision of a myoelectric prosthesis should be between the ages of 3.5 years of age and 5 years of age (222). They also stated that split-hooks were not favoured by parents for cosmetic reasons. Myoelectric prostheses were much preferred, even though there was uncertainty over correct electrode location, and fitting these electrodes was very much ‘trial and error’ (222).

Kuyper et al (2001) surveyed 224 children who were upper limb prosthesis users via case review in Utrecht, the Netherlands and stated that there was no evidence available for the functional gain that may be acquired from using myoelectric prostheses (13). In many

cases, the myoelectric prosthesis was viewed as a compromise between the simple functional response offered by a body-powered prosthesis and the passive function and superior cosmesis afforded by cosmetic prostheses. Passive, cosmetic prostheses were most commonly employed by the subjects within this review (13).

At around the same time, Routhier et al (2001) in Quebec, Canada surveyed 18 children (n=18) who were originally provided with myoelectric prostheses (223). Over half of these (53%) discontinued myoelectric prosthesis usage; other users were mainly part-time prosthesis wearers, often employing them on behalf of the parents for cosmetic reasons. Supply of the myoelectric prostheses was said to be influenced by parental wishes, in acquiring what was regarded as the most modern prosthesis type for the child (223).

Both the body-powered prosthesis and the cosmetic prosthesis do not require the intimate socket fit necessary for effective myoelectric function and control (4). This is a significant factor when children are being refitted, given the increasing volume and matching requirements that affect the prosthetic interface (124). Atkins et al (1996) suggested that improvements to the reliability of myoelectric hands and electrodes were important and necessary if full use of the prosthesis was to be achieved by the user (14).

Crandall and Tomhave (2002) surveyed 34 children retrospectively and found that the majority of those supplied with functional prostheses preferred the body-powered VC hook for functional usage (20). However, daily usage was high, with an average daily use of 9.72 hours. This suggests that other factors, as well as function, dictate prosthesis usage, the most obvious of these being cosmetic replacement (20).

As recently as 2010, Huizing et al found that 64% of children rejected their myoelectric prostheses although other prostheses were deemed to be just as poor in terms of function (52). Prosthetic rejection rates in children and young adults was said to be ‘considerable’ (52).

3.2.4 *Other factors in myoelectric prosthesis usage patterns*

Although functional myoelectric control problems are clearly the focus of this thesis, there are other factors that will influence the usage patterns associated with myoelectric prostheses. These include the following:

1. Myoelectric prostheses are relatively heavy, when compared with other similar prostheses. The use of a distally-located electrically-powered hand, incorporating a motor and other relatively heavy component parts, increases the lever effect, particularly for short residual limbs. (1, 17, 118, 224)
2. The requirement within myoelectric prostheses for a tight fitting socket, which can create excessive heat retention over the residual limb, can cause sweating and potential discomfort for the user. (13, 15, 16, 51)
3. Difficulty in learning to use the myoelectric prosthesis, combined with control problems and signal delays, can potentially restrict prosthesis uptake.(126, 161)
4. Cost can preclude myoelectric prosthesis prescription, as they are considerably more expensive than similar cosmetic or body-powered prostheses.(14)
5. Myoelectric prostheses have relatively poor durability, compared to other prostheses. Environments that are not compatible with electrical power, such as close proximity to water where frequent splashing is likely, or ones that could potentially damage intricate and relatively fragile components, such as dusty or dirty environments, will often prevent usage. (4, 51, 220)
6. Fitting electrically powered wrists, and sometimes hands, can be difficult with longer residual limbs, where there is restricted room for these components.(2)

Problems associated with myoelectric prostheses, and those previously highlighted with respect to body-powered prostheses, has meant that many potential users opt to not wear a prosthesis, or choose a light, cosmetic prosthesis instead (6, 7, 13-18, 20, 21, 44, 46, 48-51). Indeed, the most commonly prescribed upper limb prosthesis is the cosmetic prosthesis, which does not integrate active control mechanisms (14). Despite their title, these prostheses may be used to perform passive functions, such as holding or securing objects for manipulation via the sound hand. They are naturally light, and do not require a particularly intimate socket fit to be effective. The obvious visual presence of the hand means that cosmetic appeal is particularly relevant with regard to upper limb prosthesis choice; even within un-cosmetic body-powered prostheses, the most aesthetic split-hooks are normally chosen by potential prosthesis users (145).

Fraser (1998) demonstrated that basic prosthetic hand designs such as the Steeplon non-functioning hand were popular with transradial prosthesis users for passive tasks such as

lifting and carrying (7). Many prosthesis users, particularly those with a congenital limb absence, were able to employ their residual limb along with the sound side natural hand to complete most activities of daily living. Those prosthesis users with a more proximal limb absence, such as at transhumeral level, tended to wear cosmetic prostheses exclusively, and for many users, functional prostheses were seen as unreliable, with very limited functional capability (6, 7). Heat retention within the socket was implicated in producing discomfort and encouraging non-usage, a factor that was also noted in prosthesis non-usage by Berke and Nielsen (1991) (224).

Kejlaa (1993) noted that the close-fitting Munster socket may be too uncomfortable for some prosthesis users, and that socket design must take account of loads imparted (149). They also noted that the residual limb will become muscular over time, potentially leading to electrode contact problems (149). As recently as 2011, Ritchie et al reported that prosthesis users wanted both function and cosmesis, but that in particular further work into improving prosthesis functionality was needed, and users were hoping for significant improvements to prosthesis functional capabilities (45).

The evidence available in the literature therefore suggests that myoelectric prostheses have not fulfilled their functional potential. From these sources, and others as stated in previous chapters, there is some evidence to suggest that the socket and electrodes housed within the socket walls may contribute to a lack of functional effectiveness. It was therefore deemed prudent to investigate the relationship between electrode contact, socket fit and functional response and prehensor reliability via the use of a specifically-designed questionnaire. This initial investigation would provide the opportunity to attain the opinions of a number of myoelectric prosthesis users, and could indicate whether socket and electrode tightness did correlate with levels of myoelectric hand response.

The hypothesis was that a correlation would be demonstrated between the perceived intimacy of socket fit and/or electrode contact by the prosthesis user and the perceived functionality of the prosthesis as evidenced through a targeted questionnaire sent to myoelectric prosthesis users.

3.3 *Methodology*

3.3.1 *Quantitative research methods and questionnaire development*

The aim in quantitative research is to use methods used for data collection that enable clear measurement of the variables of interest. MacNee (2004) described a questionnaire as being quantitative, and an instrument used to collect specific written data with the goal of measuring answers with a numerical view (225). Questionnaires are used to gather data from participants about their knowledge, feelings and attitudes of a given subject (226). They enable the inclusion of more respondents than when using interviews to collect data (226, 227), and also enable user anonymity (228), as well as allowing the capability of obtaining data from a wide range of closely related topics and user opinions (227). The main limitations of most questionnaires are that respondents cannot widely expand their answers (225). In addition, although questionnaires have an advantage in that they can be distributed in large volumes, the response rate can be relatively low (227).

This research design is ostensibly deductive, employing data collection and data analysis (229). Questionnaires need to be designed so that both the quality of the responses and also the response rates are as high as possible (230). Self-contained questions (rather than having multi-parts to them) have been recommended in order to improve the quality of the responses and to obtain meaningful and clear answers to the questions asked (231). Having a high response rate helps to avoid bias in the results and to avoid difficulty in interpreting the results. Therefore a questionnaire should have a systematic and structured aspect to the design of the questions incorporated in it (232).

Developing an effective questionnaire is essential in recording and assimilating accurate and relevant data. A questionnaire needs to offer an appropriate balance between the depth and breadth of information requested, and the need for it to be suitable for subjects with varying academic backgrounds (80, 233). The questions need to be presented in a format which achieves the desired outcomes from a number of different respondents, so that the questions may be interpreted in the same way. The questions should be easy to read and interpret (or else discrepancies within the data could occur), should be clear and un-ambiguous, and also should not require too much time or effort on the part of the respondent to complete (80, 233). Additionally, the questions should be able to record the key facts that are required by the researcher and should be able to be interpreted clearly and easily and be tabulated in a relatively simple format (80, 233).

The questions included in a questionnaire may be ‘closed’, whereby there is one definitive answer, from a limited range available, i.e. yes or no, or ‘open’, whereby the user may offer their own individual response to a question. The questionnaire used in this study comprised of a selection of ‘open’ and ‘closed’ questions, to provide the respondent with the opportunity to include as much information as possible within a reasonable time frame.

A number of individuals were involved with the construction of this questionnaire. These included the following:

- Clinical Prosthetists from the Wirral Disablement services centre and Roehampton disablement services centre (see **Appendix A-***Questionnaires and Questionnaire development: emails to academic and professional staff)*
- Prosthesis users from the University of Salford professional patient database(see **Appendix A-***Questionnaires and Questionnaire development: Example of user questionnaire evaluation)*
- Academics experienced with questionnaire design from the University of Salford (see **Appendix A-***Questionnaires and Questionnaire development: emails to academic and professional staff)*
- Therapists from the University of Salford (see **Appendix A-***Questionnaires and Questionnaire development: emails to academic and professional staff)*

The questionnaire used for this study also contained certain questions and sections based on those previously published by Biddiss and Chau (2007b) (214) plus newly developed sections specifically designed to provide data for determining socket and electrode tightness and myoelectric hand response. The questionnaire was piloted using upper limb myoelectric prosthesis users (n=2), and was designed to be completed by myoelectric prosthesis users with transradial limb absence. Ethical approval was granted by the University of Salford Ethics Committee and also through the appropriate NHS ethics systems (see **Appendix B**-*Ethical approval and related documents*).

3.3.2 *Questionnaire design and distribution-phase 1.*

Distribution of the questionnaire occurred in two phases. Phase 1 involved the participation of four prosthetic centres in the United Kingdom (UK) who agreed to distribute

a questionnaire following consultation and ethical approval. A fifth centre was subsequently included, and following further consultation, distribution of a revised version of the questionnaire to myoelectric prosthesis users was undertaken. However this revised questionnaire only mainly affected sections A and B, with the only substantive changes within section B concerning the types of activities that the prosthesis users were undertaking.

The questionnaire consisted of four distinct sections (A, B, C, D). Sections A and B were based on the questionnaires developed by Atkins et al (1996) (14), Kyberd et al (1998) (17) and Biddiss and Chau (2007b) (214). Section A was designed to provide historic data from the respondent. In section B, questions were developed to illustrate the range of functional uses and normal daily activities that each type of prosthesis was employed for. Section C was designed to evaluate the responsiveness of the myoelectric prehensor when compared to the perceived tightness or looseness of the socket plus that of the electrodes fitted in the prosthesis. The remaining sections were designed to provide useful generic data which could be contrasted with the results from Section C as well as data previously acquired by previous upper limb prosthesis usage questionnaires. Section D was to be filled out if the respondent had rejected their myoelectric prosthesis. The full questionnaire (phase 1) may be found in **Appendix A**-*Questionnaires and Questionnaire development: phase 1 questionnaire***,** along with a pilot questionnaire illustrating how evidence was collated from prosthesis users during its formation**.** The four questionnaire sections are detailed within the following sections.

3.3.2.1 *Section A*: *General prosthesis user information*

This section included personal background information and information relating to the cause and date of limb loss. Information from this section provided a reference with regard to daily hours that the prosthesis was used and any link between generic circumstances, prosthesis functionality and prosthesis usage. The prosthesis users' names and addresses were not requested, and they remained anonymous within a system classified using dates of birth with respective letters of the alphabet, thereby maintaining user confidentiality. This section consisted of six questions in total.

Data relating to the following questions were therefore collated and are presented in section 3.5**:**

- Gender / date of birth;

- Date / Cause (if applicable) of limb absence;
- Prosthesis usage rates (hours per day / days per week).

3.3.2.2 *Section B*: *Types of prosthesis and routine activities undertaken*

This section requested information regarding the types of prosthesis currently and previously used by each subject and activities routinely undertaken by the prosthesis user. Some users may have previously used body-powered prostheses, or would be using them either in conjunction with, or instead of, their myoelectric prostheses. In this case, the questionnaire was designed to be able to provide useful data which would enable a comparison to be made between the usability of these prostheses with respect to the activities that were listed by each respondent.

Questions relating to the following, which contrasted usage patterns, were better illustrated via the form of charts, and are therefore included graphically in section 3.5:

- Prosthesis type / user rating for 1) functional use, 2) overall usability;
- Length of prosthesis usage since first prescription;
- Types of activities undertaken with each prosthesis: Outdoor work, Indoor work, socialising, sports, gardening or carrying undertaken using each type of prosthesis.

3.3.2.3 *Section C*: *Perceived socket and electrode contact variations and resultant prehensor response*

Section C asked the respondents to provide information with respect to the perceived socket fit of their myoelectric prosthesis and a comparison where possible to that of their cosmetic prosthesis. This section included questions regarding the users' own perception of the socket fit and electrode contact, with both being rated on a Likert scale (12, 48).

The user was asked to rate the tightness of both the electrode and the socket via the following questions:

1) Please rate the **general tightness** of your myoelectric socket, by placing an 'X' on the scale line below:

Very loose= 0_____10= Very tight

2) Please rate the **tightness of the electrodes** within your myoelectric socket, by placing an 'X' on the scale line below:

Very loose= 0_____10= Very tight

The rating from each user was expressed numerically by using a 10cm scale line, which was then split into 10 x 1cm sections, each one representing a number from 1 to 10 (1 being the loosest rating, 10 being the tightest rating). The number correlating most closely to the position of the 'X' was then recorded as the user's rating for the respective socket tightness or electrode tightness.

Likert scales such as this have been used on numerous studies for this type of questionnaire, notably by Davidson (2004) (48) and Pylatiuk et al (2007) (12).

The responsiveness and potential usability of the myoelectric hand was also ascertained in terms of prosthesis controllability using two key questions:

1. Does the prehensor ever activate **on its own** when you don't want it to?
2. Does the prehensor ever **fail to activate** when you want it to?

Question (1) related to the potential production of motion artefacts, which could cause the myoelectric hand (or other prehensor) to activate on its own, without the control of the prosthesis user. This lack of myoelectric hand control would most likely be as a result of movements between the socket and electrodes and the residual limb.

Question (2) related to the ability of the prosthesis user to employ the myoelectric hand when they wanted to operate it. A general lack of good contact, or a problem with the signal acquisition, would cause this activation failure to occur.

The following options/answers were available to the prosthesis user for each of these questions:

- Never = (most reliable prehensor activation)
- Rarely
- Sometimes
- Often = (least reliable prehensor activation)

The user was again asked to ring the most appropriate answer in relation to their myoelectric hand and its responsiveness. These results were compared to information correlating the security or tightness of the prosthetic socket and the electrode contacts with resultant prehensor control reliability and the effect of this on prosthesis usage.

The results from these responses were designed to provide information regarding the relationship between socket fit, electrode contact and prosthesis functionality related to prehensor control.

Questions relating to the following were also included in **section C** to provide critical information about the socket interface:

- Ease of prosthesis use;
- User evaluation of socket / electrode tightness of fit (tightness rating scale, 0 - 10);
- User evaluation of prehensor response.

3.3.2.4 *Section D*: This section contained questions for prosthesis users enquiring why, if applicable, they had ceased to wear their myoelectric prosthesis. All respondents was asked to fill in all sections of the questionnaire, except section D, which was only to be filled in if a myoelectric prosthesis had been rejected at any stage previously.

3.3.2.5 *Pilot Users*

The two Pilot users took approximately 15 minutes on average to complete the questionnaire. A version of the pilot questionnaire is included within **Appendix B-** *Questionnaires.* The pilot users were asked to fill out comment boxes after each question.

3.3.2.6 *Distribution*

The questionnaire was distributed to current adult transradial myoelectric prosthesis users, or past users over 18 years of age, at each of the following four clinical prosthetic centres within the UK whose caseload included adequate numbers of myoelectric prosthesis users:

- Bristol Disablement Service Centre;
- Crystal Palace Disablement Service Centre;
- Roehampton Disablement Service Centre;
- Wirral Disablement Service Centre;

A total of 46 questionnaires were distributed as part of this 'phase 1' of the analysis. Of these, 24 were completed and returned, including those (n=4) which formed part of the pilot study (a 48% response rate). The response rate for this study was lower than the 89% cited by Glyn and Hunter (1986) (93) and lower than the 69% recorded by Kyberd et al (1998) (17). No follow up was performed although this may have improved response rates, as noted by Crandall and Tomhave (2002) (20).

3.4 *Questionnaire design and distribution- Phase 2*

The original questionnaire (**Appendix A-***Questionnaires and Questionnaire development: phase 1 questionnaire*) was also provided for distribution to staff at the Withington Disablement Services Centre, Manchester, United Kingdom, in addition to those centres listed in section 3.3.1. However, staff at this centre, led by the clinical Rehabilitation Consultant, provided further consultations to the phase 1 questionnaire design before this was distributed to prosthesis users associated with this centre. The team at Manchester DSC decided that they would like certain inclusions and changes to be made to the questionnaire prior to distribution to prosthesis users who attended this centre.

3.4.1 *Extra questions that were inserted prior to phase 2*

Extra questions inserted into the questionnaire prior to phase 2 distribution included the following:

- Type of prosthesis manufacturer (if known)

3.4.2 *Changes to the questions within phase 2*

Primarily, the changes made to the questionnaire prior to phase 2 distributions were made to the questions associated with prosthesis user activities (section B). The following lists of activities were those included during phase 1 in section B of the questionnaire undertaken using either a body-powered or myoelectric type of prosthesis:

Phase 1 questionnaire

- Outdoor work
- Indoor work
- Socialising
- Sports
- Gardening
- Carrying

These activities were deemed to be too generic, and were replaced by the following options on the advice of the Occupational therapist at Withington disablement services centre. In addition, the use of a cosmetic prosthesis would also be included with regard to these activities in addition to the other, functional prostheses:

Phase 2 questionnaire

- **Outdoor activities undertaken with each type of prosthesis**:
- Socialising (although this could have been classified as either indoor or outdoor)
- Playing sports
- Using a drill
- Washing a car
- Holding tools
- Lifting bags

- **Indoor activities undertaken with each type of prosthesis**:
- Tying laces
- Holding objects
- Turning pages
- Open bottle

In addition, a section on activities was added that related to those undertaken using cosmetic prostheses, as well as those that were undertaken by body-powered and myoelectric prostheses. This allowed for all types of prostheses to be assessed rather than those predominantly prescribed for functional purposes.

Also, in section C, the' likert' rating scales were changed, to allow for easier noting and recording of the tightness rating by the following question options:

1) Please rate the **general fit** of your myoelectric socket on the scale below, by placing a ring around the appropriate number: the ***lower*** the number, the ***looser*** the fit.

1 2 3 4 5 6 7 8 9 10

2) Please rate the fitting of the **electrodes** within your myoelectric socket on the scale below by placing a ring around the appropriate number: the ***lower*** the number, the ***looser*** the fit.

1 2 3 4 5 6 7 8 9 10

3.4.3 *Changes to the distribution criteria*

In phase 1, the questionnaire was distributed to only those users with a transradial level of limb absence. The revised, phase 2 questionnaire was distributed to adults (n=40; over 18 years old) who had been prescribed myoelectric prostheses between the years 2000 and 2009 at **all** levels of limb absence at Manchester Disablement Service Centre, Withington Hospital, Manchester. No distinction was made with regard to the cause of limb absence. The revised questionnaire distributed in phase 2 can be seen in **Appendix A**-*Questionnaires and Questionnaire development: phase 2 questionnaire.*

From the 40 questionnaires distributed, 12 were completed and returned, including the two which formed part of the pilot study (a 30% response rate). The response rate for this study was lower than that seen in phase 1, although no reasons could be deduced as to why this was the case. A follow up is planned for 6-12 months following the initial distribution of the questionnaire as this has been stated to improve response rates (20).

The results from each questionnaire were carefully recorded in a tabular format, reproduced graphically in section 3.5. In addition, the results obtained from both phases of distribution have been summatively as well as individually recorded where appropriate.

3.5 *Questionnaire results*

3.5.1 Section A- General prosthesis user information

Phase 1 age range: 21-72 years, with a mean age of 44.9

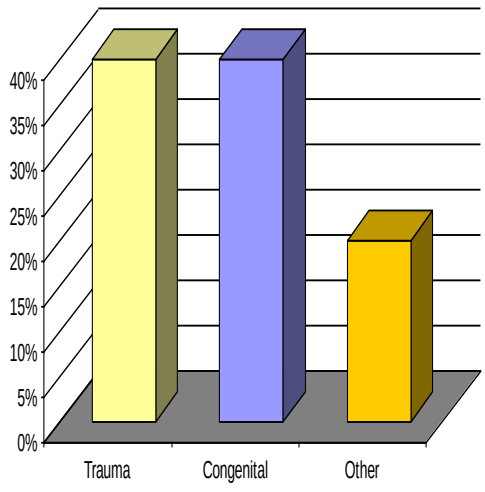
Phase 2 age range: 23-68 years, with a mean age of 44.6

Combined age range: 21-72 years, with a mean age of 44.8

The mean age of all the respondents for both phases was 44.8 +/- 27.2 years

The mean age within this survey was therefore higher than those quoted by Datta et al (2004) and Kejlaa (1993), which were 24.1 years and 32.8 years respectively, but lower than the 56.4 years average age quoted by Roeschlein and Domholdt (1989) (21, 149, 221). These figures reflect the main causative factors for upper limb absence, such as trauma and congenital absence, related to upper limb prosthesis users (71, 97-102, 236). This contrasts with lower limb absence, where the average age of limb users will be significantly higher due to the mainly vascular conditions that are linked to lower limb amputation (95, 98).

3.5.1.2 *Cause of limb absence*



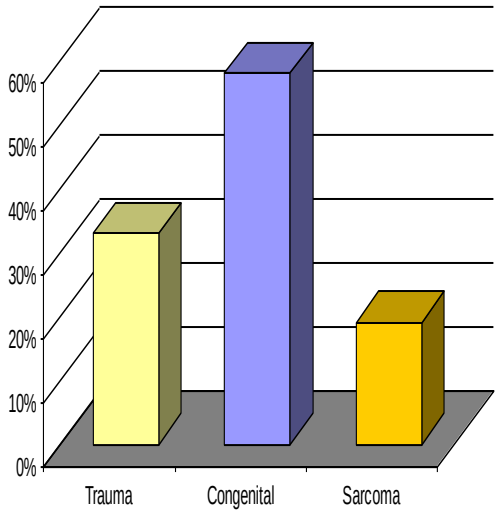


Fig 3.1a: Cause of limb absence- *phase 1* **Fig 3.1b:** Cause of limb absence- *phase 2*

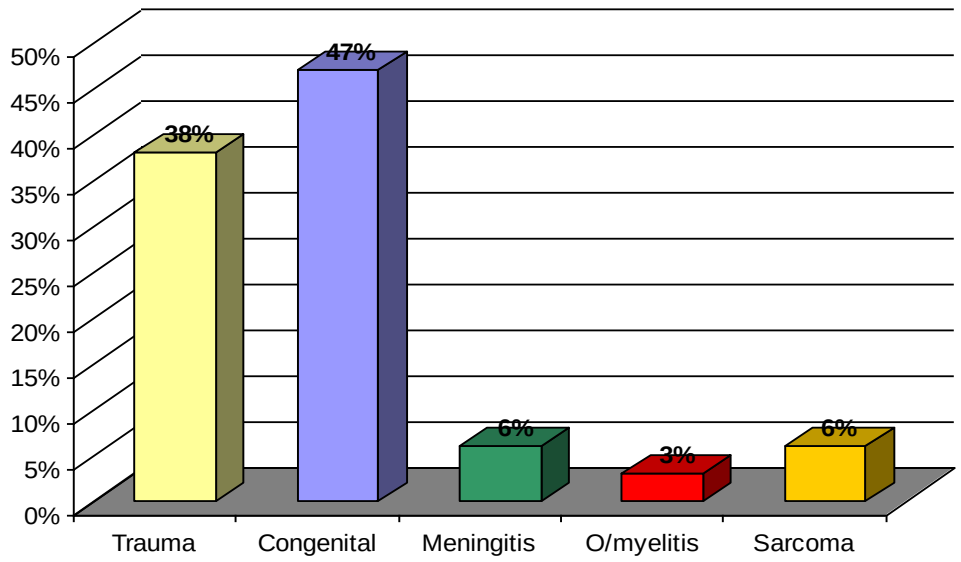


Figure 3.1c: Cause of limb absence-*Combined results from phase 1 and phase 2*

The majority of respondents had a congenital limb absence (47%) or limb absence due to trauma (38%), see **figure 3.1c**. 'Other' causes (phase 1, **figure 3.1a**) included osteomyelitis and meningitis and sarcoma. Osteomyelitis and meningitis were not reported during phase 2 (**figure 3.1b**). Although the single largest cause of limb absence was congenital within this survey, trauma was stated as the most common cause of limb absence by Datta et al (2004) and Kejlaa (1993) (21, 149). However, cancer was quoted as being responsible for 11% of limb amputations by Kejlaa (1993), which is relatively close to the 6% overall combined figure recorded in this survey (149). Little information is available regarding meningitis as a main cause of limb absence within other similar surveys, even though the figure within this survey is the same as that for cancer (6%).

3.5.1.3 *Gender of the respondents*

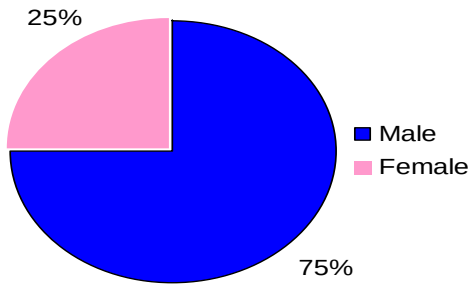


Figure 3.2: Gender of prosthesis user respondents-*combined results from phase 1 and phase 2*

The majority (75%) of respondents were males (**see figure 3.2**). Remarkably, in both phases the identical gender proportion was demonstrated (3: 1, Males: Females). This is significantly lower however than the 8:1 ratio of males: females quoted by Gaine and Smart (1997) and Roeschlein and Domholdt (1989) (44, 221). Jain (2000) quoted a larger proportion of purely congenital limb absence amongst Males (65%), although Kyberd et al (1998) stated that the cause of limb absence amongst male prosthesis users surveyed in Oxford tended to be trauma, rather than congenital (17, 105). In females, this was the reverse, with the left side being more likely to be affected (17). Females were quoted as being more likely to reject their prosthesis by Biddiss and Chau (2007b), and they also stated that prosthesis users with congenital absence were also more likely to reject their prosthesis (214).

3.5.2 *Section B: Type of prosthesis/ activities performed when using the prosthesis*

3.5.2.1 *Functional prostheses types worn (in addition to myoelectric prosthesis)*

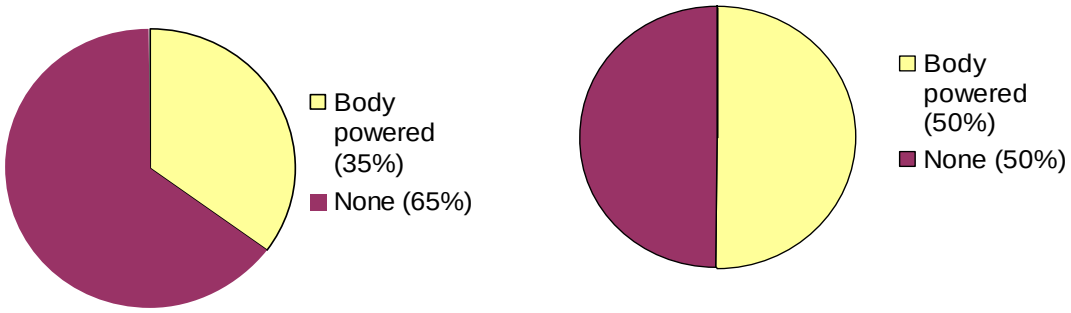


Figure 3.3a: Functional prostheses types- *phase 1* **Fig 3.3b:**Functional prostheses types- *phase 2*

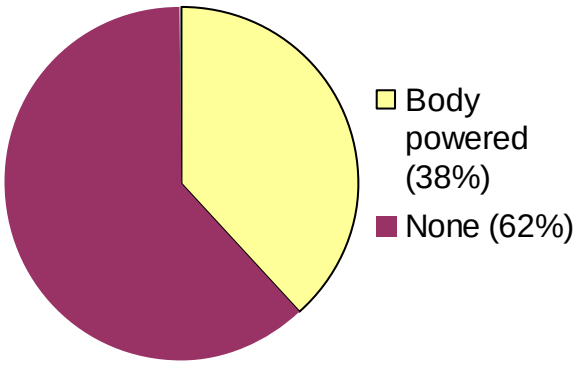


Figure 3.3c: Functional prostheses types worn- *Combined results from phase 1 and phase 2*

The combined data for the provision of alternative prostheses demonstrated that body-powered prostheses were the devices of choice with 38% of respondents also supplied with this prosthesis type in addition to a myoelectric prosthesis (see **figure 3.2c**). This indicates that more prosthesis users were supplied with a myoelectric prosthesis than a body-powered prosthesis. By contrast, previous surveys have shown that more users were supplied with a body-powered prosthesis than a myoelectric prosthesis (6). These results suggest that either the prescription of body-powered prostheses has declined over time or perhaps, more likely that the prosthesis users who had been supplied with a body-powered prosthesis and were satisfied with this had not wished to be considered for the provision of a myoelectric prosthesis. In addition, no respondents had rejected their myoelectric prostheses, even though 38% had also been supplied at some point with a body-powered prosthesis.

3.5.2.2 *Myoelectric prosthesis usage in hours / day*

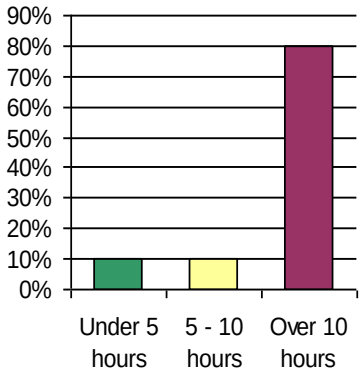


Figure 3.4a: Myoelectric usage- *phase 1*

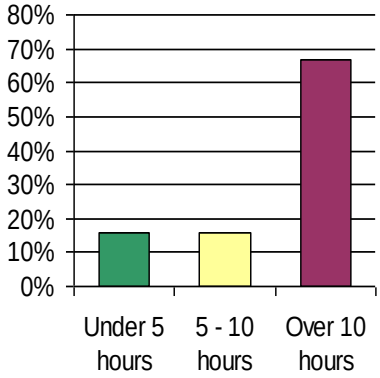


Figure 3.4b: Myoelectric usage- *phase 2*

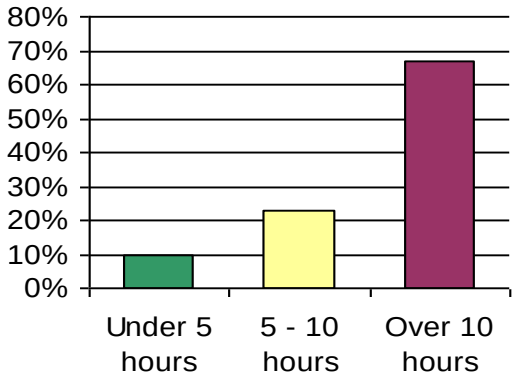


Figure 3.4c: Myoelectric prosthesis usage in hours / day- *Combined results*

A large majority of respondents (67%) wore a myoelectric prosthesis for more than 10 hours a day, which suggested a high level of overall satisfaction with the prosthesis (see **figure 3.4c**). This high level of daily usage, amongst adult myoelectric prosthesis users, confirmed that quoted by Millstein et al (1986), Glyn and Hunter (1986), Crandall and Tomhave (2002), Biddiss and Chau (2007b) and Pylatiuk et al (2007), who all quoted average myoelectric prosthesis usage as being greater than 8 hours per day (12, 20, 93, 147, 214). However, Balance et al (1989) found that body-powered prosthesis users were more likely to wear their prostheses full time during the day, with myoelectric users only opting to wear their prostheses part time (51).

3.5.2.3 ***Most functional Prosthesis*** *(for those supplied with both Body-powered and Myoelectric)* ***(%)***

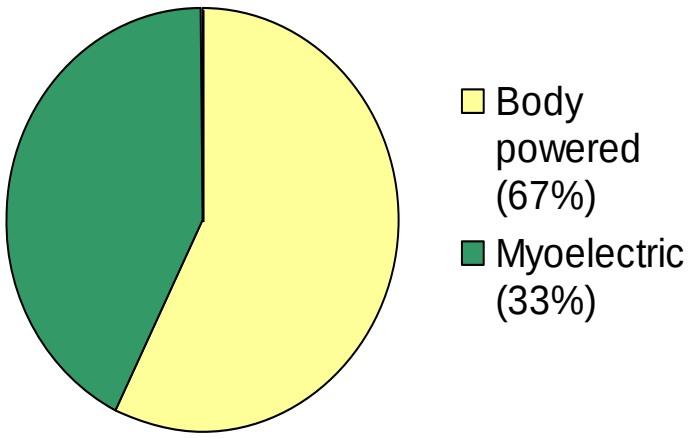


Figure 3.5: Most functional prosthesis-*Combined results*

Similarly to the results for gender distribution, there was an identical proportion in both phases for the users rating of the best functional prosthesis. The combined and individual results from both phase 1 and phase 2 (see **figure 3.5**) showed that 67% of prosthesis users surveyed who wore both body-powered and myoelectric prostheses considered the body-powered prosthesis to be the more functional than the myoelectric prosthesis. For both phases, an

identical proportion of respondents preferred the body-powered prosthesis in terms of functional usage (hence the need for only one illustration).

As previously discussed in section 3.2, body-powered prostheses have generally been recognised as being more functional in most surveys, with the body-powered voluntary closing split-hook recognised as the most functional prosthetic device (Trost & Rowe, 1983), (Kruger and Fishman, 1993), (Crandall and Tomhave, 2002), (Biddiss and Chau, 2007a) (6, 20, 204, 234).

3.5.2.4 ***Best overall prosthesis*** *(for those supplied with both types)*

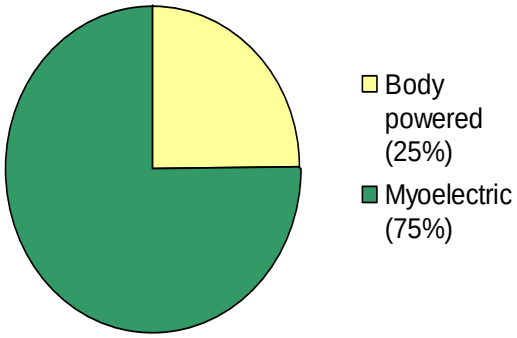


Fig 3.6a: Best overall prosthesis-*phase 1*

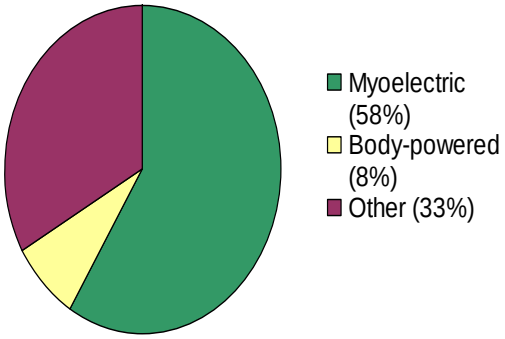


Fig 3.6b: Best overall prosthesis- *phase 2*

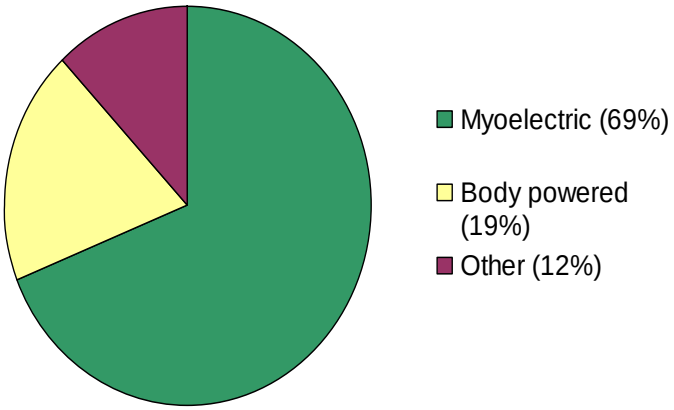


Fig 3.6c: Best overall prosthesis- *Combined results*

The myoelectric prosthesis was considered to offer the best overall features (i.e. cosmesis and function), by 69% of the prosthesis users who responded to this question (see **figure 3.6c**). This fact suggests that the additional function provided by the body-powered prosthesis was outweighed by the additional cosmesis that is acquired from the myoelectric prosthesis. This may be borne out by Pylatiuk et al (2007) who stated that myoelectric prosthesis users surveyed had the highest contentment with the cosmesis, rather than the function, of their myoelectric prostheses (12).

When analysing prostheses worn by children, Crandall and Tomhave (2002) retrospectively analysed the provision of numerous prostheses of different variants to 14 children, and found that 50% preferred the body-powered prosthesis overall, with only 14% preferring the myoelectric prosthesis (20). The other children preferred the cosmetic prosthesis. However, it has been shown that a prosthesis user will accept a prosthetic limb if it is comfortable, cosmetic and functional, depending on their specific requirements and aspirations (Burger & Marincek, 1994) (16).

3.5.2.5 *Activities undertaken using different prostheses*

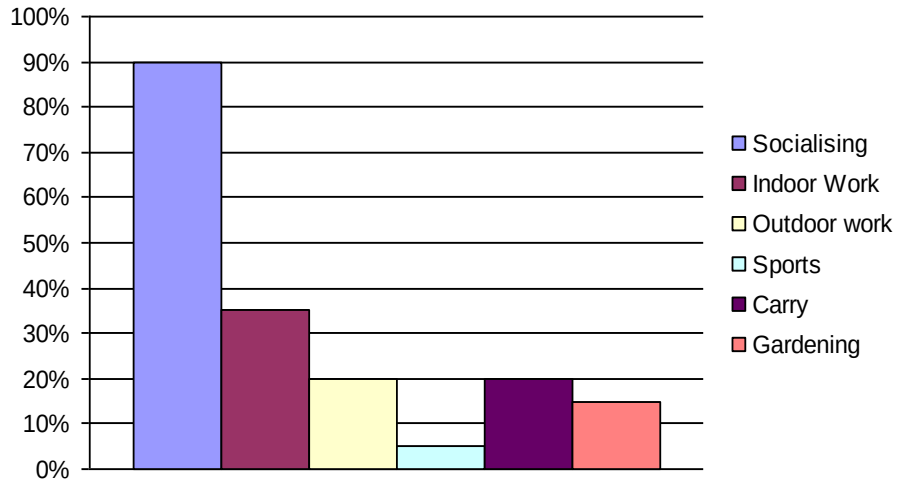


Figure 3.7a: Activities undertaken using the myoelectric prosthesis-*phase 1*

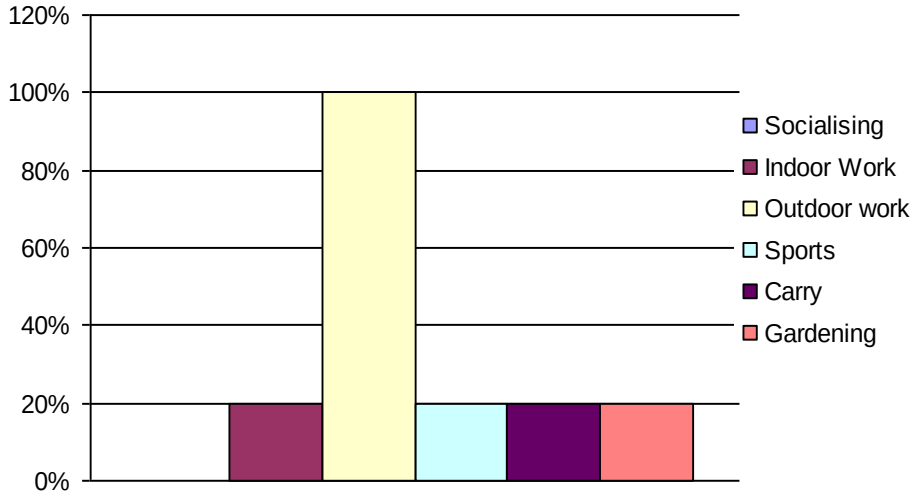


Figure 3.7b: Activities undertaken using the body-powered prosthesis-*phase 1*

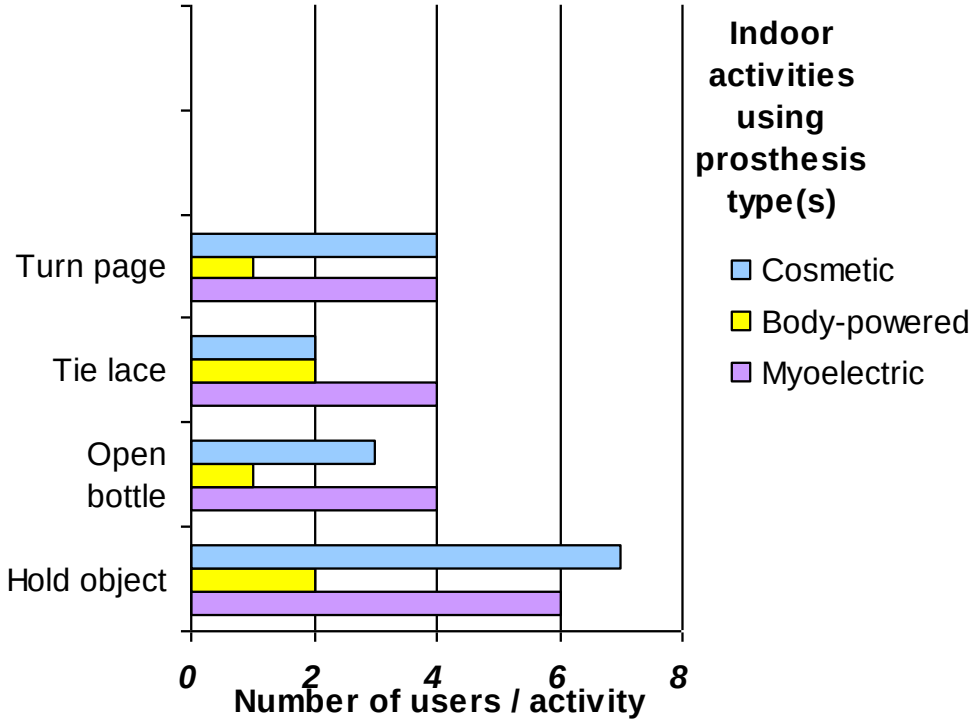


Figure 3.8a: Indoor activities undertaken using prosthesis/prostheses-*phase 2*

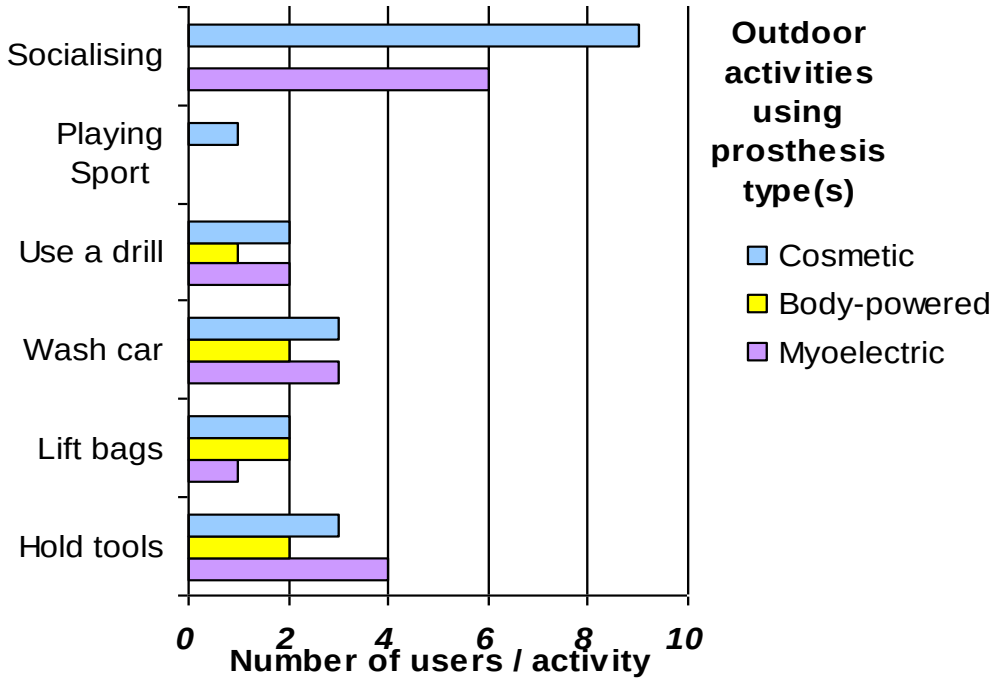


Fig 3.8b: Outdoor activities undertaken using prosthesis/prostheses-*phase 2*

The questions within each questionnaire (phase 1 and 2) varied significantly. Consequently, the results are only presented in the original formats and not combined. However, even when analysing these singular illustrations, it is still apparent that there are many basic similarities between each set of results.

It is clear whilst analysing the results from phase 1 that there is a distinct difference between types of tasks employed for myoelectric and body-powered prostheses (see **figures 3.7a & 3.7b**). Whereas the myoelectric prosthesis is employed mainly for socialising (90% of myoelectric limb users use their prosthesis whilst doing this), the body-powered prosthesis is employed for outdoor work by every wearer of this prosthesis type. Interestingly, both types of prostheses are employed in similar proportions for gardening and carrying objects (~20% of prosthesis users employing both types use their prostheses during these activities).

It can also be seen that same majority of prosthesis users surveyed in phase 2 (90%) also employed their myoelectric prostheses whilst socialising (**figure 3.7a**). None of the prosthesis users who were supplied with a body-powered prosthesis employed them for this purpose. Other activities more associated with function, such as indoor or outdoor work,

involved the use of the myoelectric prosthesis to a much smaller extent (35% and 20% respectively). This was reflected in the fact that none of the prosthesis users wore their body-powered prosthesis when socialising, whereas this was the most popular use for cosmetic prostheses and myoelectric prostheses (**figure 3.7b**).

Cosmetic prostheses and myoelectric prostheses offered almost symmetrical patterns with regard to overall usage (**figures 3.8a & 3.8b**). The results demonstrated that body-powered prostheses were used generally more infrequently, although it should be remembered that only 30% of the users surveyed had access to a body-powered prosthesis. Taking this figure into account, it is clear that for those users that had access to them, body-powered prostheses were used for many functional tasks, particularly those outdoors (**figure 3.8b**).

Similarly, Jones and Davidson (1995) also found that the split hook for a body-powered prosthesis was very good for lifting and carrying objects (79), whilst Kruger and Fishman in 1993 demonstrated that body-powered hooks were more commonly used for functional daily tasks than other devices (234).

Some users surveyed in this study were able to use each type of prosthesis for tying a shoelace (**figure 3.8b**), despite finite control of any functional prosthesis being difficult, according to Fraser (1998) (7). The actual usage employed by the prosthesis during this task however is unknown; the prosthesis may simply be employed to secure one lace, whilst the sound arm completes the intricate movements. It has been stated that individuals with only one absent limb can utilise the remaining sound arm for most daily tasks, with Glynn and Hunter (1986) finding that around 90% of the activities of daily living may be accomplished one handed (93).

The similar patterns of usage for cosmetic and myoelectric prostheses demonstrated in this study (**figures 3.8a & 3.8b**) suggest that cosmetic prostheses are also able to provide reasonable levels of function, as previously documented (7). Mirroring this, Biddiss and Chau (2007b) found that ~27% of myoelectric prosthesis users employed their prostheses for purely cosmetic reasons (214). Social attitudes regarding cosmesis, and the decline of more traditional manual roles, may have contributed to a change in emphasis with regard to prosthesis usage and wear (5). This was reflected in the fact that none of the prosthesis users wore their body-

powered prosthesis when socialising, whereas this was the most popular use for cosmetic prostheses and myoelectric prostheses (**figures 3.7a & 3.7b**)

The following results section illustrates the users' perceptions of socket tightness and electrode tightness and the responsiveness of the prehensor. The graphs illustrate the link between these two key areas of interest of this thesis.

3.5.3 *Section C: Perceived tightness versus prehensor response– Phase 1*

3.5.3.1 *Delayed hand response versus socket tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever fail to activate when you want it to?"*** matched against user's ratings for socket tightness.

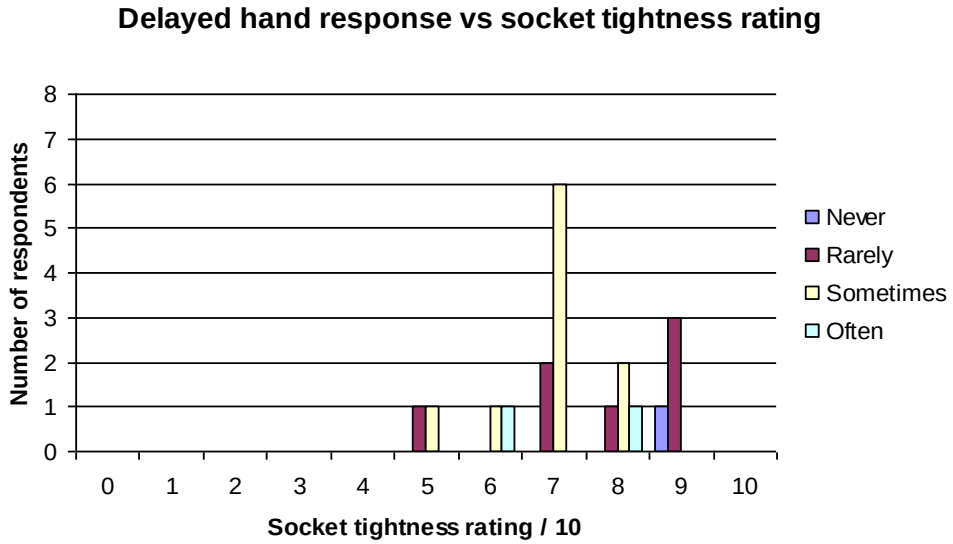


Fig 3.9(a): Delayed myoelectric hand response versus socket tightness

Average Socket tightness for appropriate response regarding Delayed hand response:

Never:	9.00	(1x9 / 1)
Rarely:	7.71	(3x9 + 1x8 + 2x7 + 1x5 / 7)
Sometimes:	6.78	(1x8 + 6x7 + 1x6 + 1x5 / 9)
Often:	7.00	(1x8 + 1x6 / 2)

The socket tightness ratings were relatively spread out for the prosthesis users surveyed within phase 1, with ratings between 5 out of 10 and 9 out of 10 for all users. Only 1 prosthesis

user stated that their myoelectric hand never had a delayed response. This user had the highest socket tightness rating that was noted, along with one other user who rarely encountered a delayed response from their myoelectric hand. However, another user with the same level of myoelectric hand response only rated the tightness of their socket as 5 out of 10, whilst two other users, with tightness ratings of 6 out of 10 and 8 out of 10 respectively both encountered delayed myoelectric hand responses 'often'.

3.5.3.2 *Delayed hand response versus electrode tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever fail to activate when you want it to?"*** matched against user's ratings for electrode tightness.

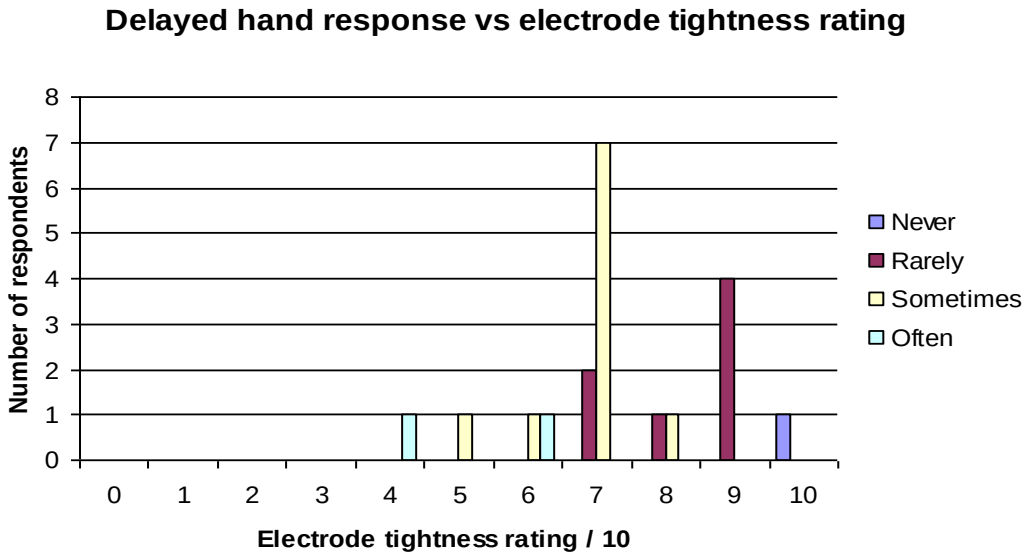


Fig 3.9(b): Delayed myoelectric hand response versus electrode tightness

Average Electrode tightness for appropriate response regarding Delayed hand response:

Never:	10.00	(1x10 / 1)
Rarely:	8.29	(4x9 + 1x8 + 2x7 / 7)
Sometimes:	6.80	(1x8 + 7x7 + 1x6 + 1x5 / 10)
Often:	5.00	(1x6 + 1x4 / 2)

The only prosthesis user who stated that their myoelectric hand never encountered delayed prehensor response was the only one to give their electrode tightness rating a top score of 10 out of 10. By contrast, the only user to rate their socket at the lowest tightness rating

noted throughout the survey, 4 out of 10, encountered delayed prehensor response ‘often’. The distinction between scores allocated to each category was quite clearly defined for delayed prehensor response with regard to electrode tightness ratings, with the average rating for each category steadily decreasing from a maximum of 10 out of 10 for ‘rarely’ to a figure of only 5 out of 10 for ‘often’.

3.5.3.3 *Unwanted hand response versus socket tightness rating*

The following data correlates to users’ response to the question**: *“Does the prehensor / hand ever activate on its own when you don’t want it to?”*** matched against user’s ratings for socket tightness.

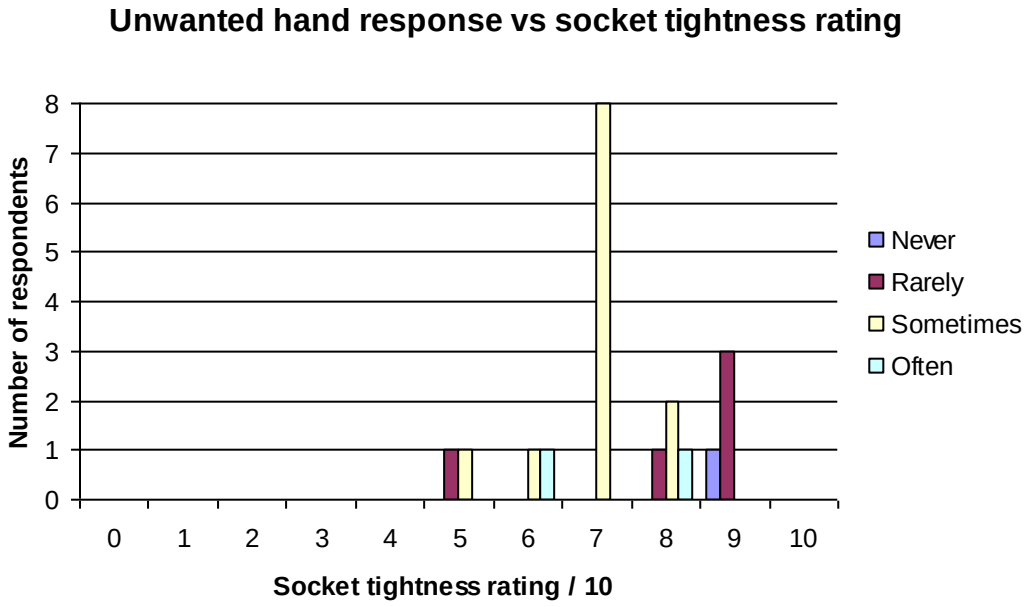


Fig 3.10(a): Unwanted myoelectric hand response versus socket tightness

Average Socket tightness for appropriate response regarding Unwanted hand response:

Never:	9.00	(1x9 / 1)
Rarely:	8.00	(3x9 + 1x8 + 1x5 / 5)
Sometimes:	6.92	(2x8 + 8x7 + 1x6 + 1x5 / 12)
Often:	7.00	(1x8 + 1x6 / 2)

The socket tightness ratings for unwanted hand response are very similar to those illustrated in **figure 3.9(a).** The only user again who stated that they never had a delayed

myoelectric hand response had the highest socket tightness rating of 9 out of 10. However, for unwanted hand response, it can be noted that by far the largest number of responses with regard to unwanted hand response were in the 'sometimes' category. A full 70% of those surveyed here stated that they had unwanted hand response either 'sometimes' or 'often'.

3.5.3.4 *Unwanted hand response versus electrode tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever activate on its own when you don't want it to?"*** matched against user's ratings for electrode tightness.

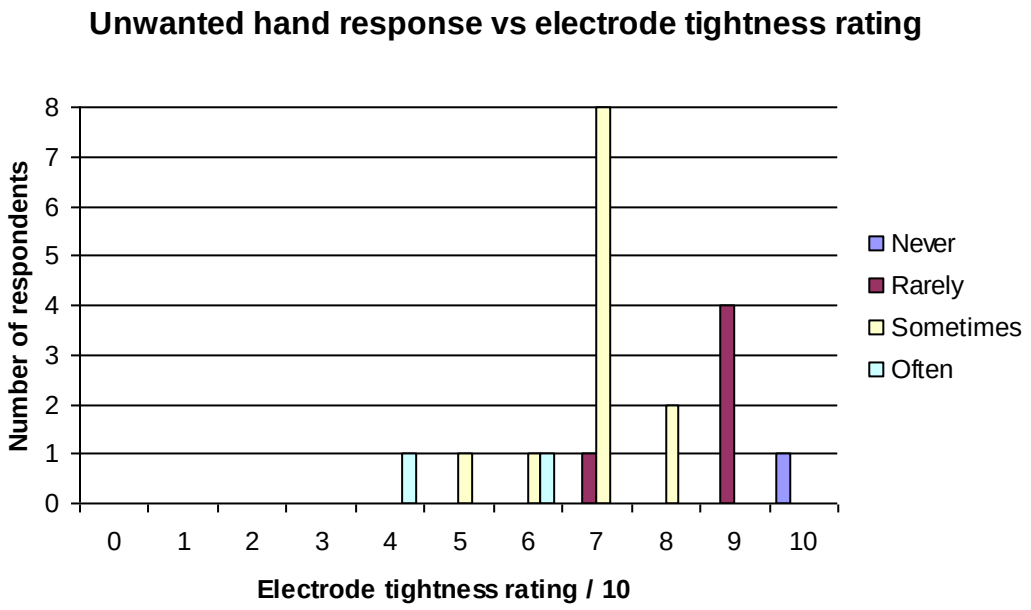


Fig 3.12(b): Unwanted myoelectric hand response versus electrode tightness

Average Electrode tightness for appropriate response regarding Unwanted hand response:

Never:	10.00	(1x10 / 1)
Rarely:	8.60	(4x9 + 1x7 / 5)
Sometimes:	6.92	(2x8 + 8x7 + 1x6 + 1x5 / 12)
Often:	5.00	(1x6 + 1x4 / 2)

The results here again reflect the large number of 'sometimes' and 'often' responses noted earlier for unwanted hand response. However, the correlation between high electrode

tightness ratings and less unwanted hand response were more clearly defined for electrode tightness, when compared to socket tightness.

3.5.4 *Section D: Reasons for prosthesis rejection*

No users rejected their myoelectric prostheses from those surveyed in phase 1

3.5.5 *Section C: Perceived tightness versus prehensor response– Phase 2*

3.5.5.1 *Delayed hand response versus socket tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever fail to activate when you want it to?"*** matched against user's ratings for socket tightness.

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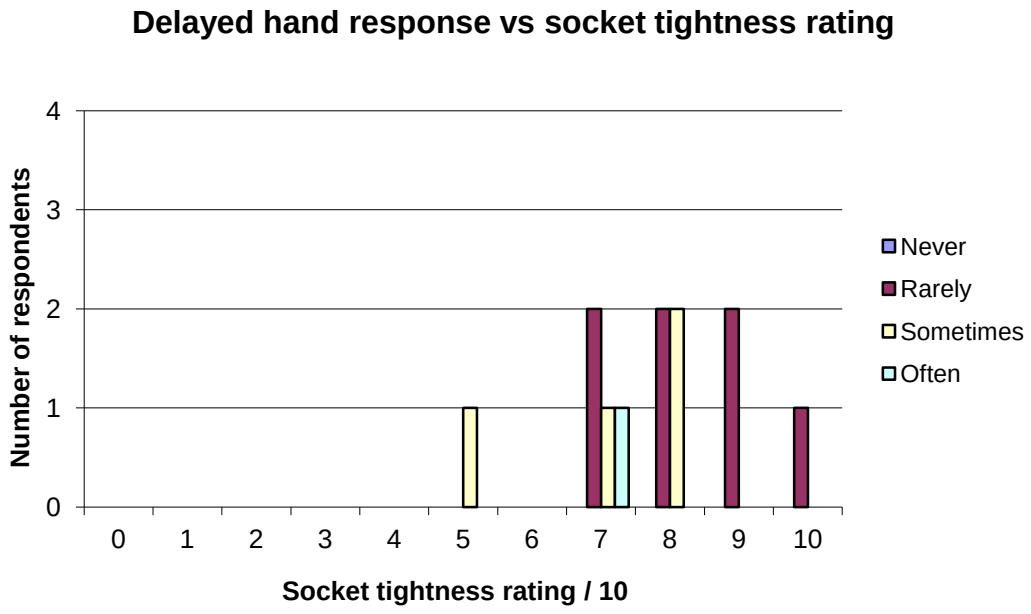


Fig 3.11(a): Delayed myoelectric hand response versus socket tightness

Average Socket tightness for appropriate response regarding Delayed hand response:

Never:	-	
Rarely:	8.60	(1x10 + 2x9 + 2x8 + 2x7 / 7)
Sometimes:	7.00	(2x8 + 1x7 + 1x5 / 3)
Often:	7.00	(1x7 / 1)

No prosthesis users noted that they 'Never' had delayed response from their myoelectric hand within those surveyed in phase 2. The majority of those surveyed noted that they 'Rarely' had a delayed response from their myoelectric hand, but 40% had a delayed response 'Sometimes' and 1 had a delayed response 'Often'. There was a clear difference between the socket tightness rating for those users who noted that they 'Rarely' had delayed myoelectric hand response (8.6 average) and those that encountered these problems 'Sometimes' or 'Often' (7.0).

3.5.5.2 *Delayed hand response versus electrode tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever fail to activate when you want it to?"*** matched against user's ratings for electrode tightness.

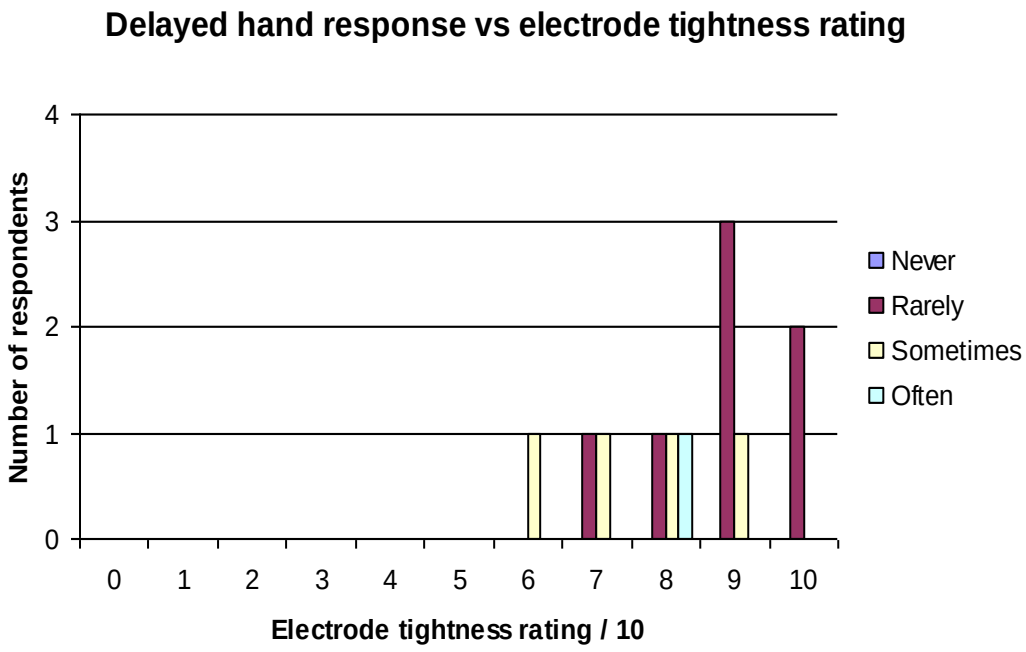


Fig 3.11(b): Delayed myoelectric hand response versus electrode tightness

Average Electrode tightness for appropriate response regarding Delayed hand response:

Never:	-	
Rarely:	8.86	(2x10 + 3x9 + 1x8 + 1x7 / 7)
Sometimes:	7.50	(1x9 + 1x8 + 1x7 + 1x6 / 4)
Often:	8.00	(1x8 / 1)

The electrode tightness rating did not vary as significantly with respect to the hand response during phase 2 as much as was noted in phase 1. Even though there was a larger average tightness rating noted when delayed response occurred ‘Rarely’, the one user who encountered a delayed myoelectric hand response ‘Often’ rated the tightness of their electrode contacts as relatively high, with a score of 8 out of 10.

3.5.5.3 *Unwanted hand response versus socket tightness rating*

The following data correlates to users’ response to the question**: *“Does the prehensor / hand ever activate on its own when you don’t want it to?”*** matched against user’s ratings for socket tightness.

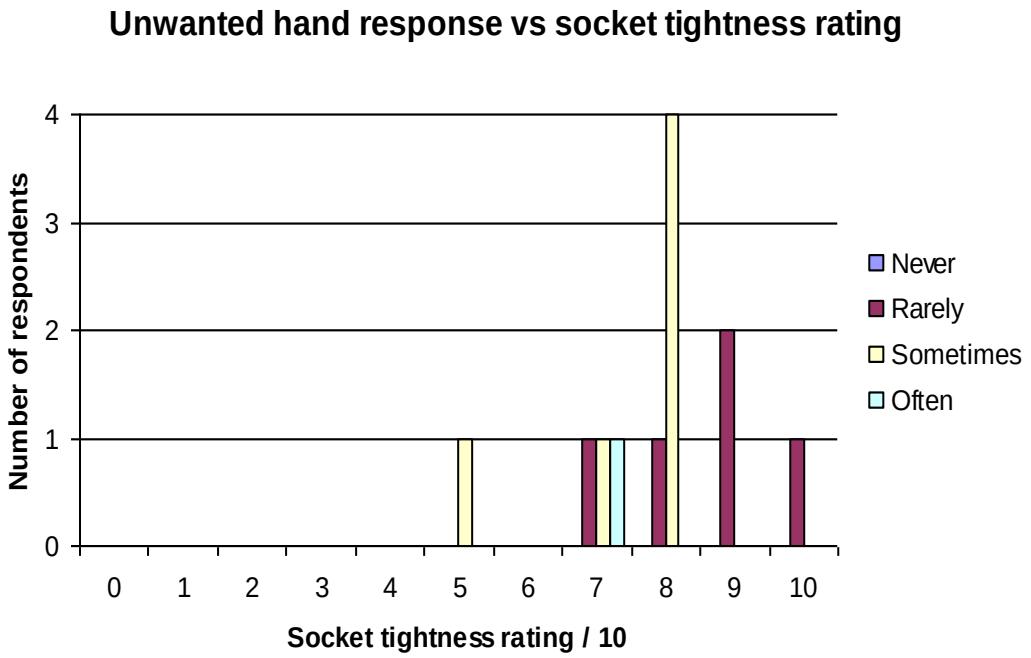


Fig 3.12(a)*:* Unwanted myoelectric hand response versus socket tightness

Average Socket tightness for appropriate response regarding Delayed hand response:

Never:	-	
Rarely:	8.60	(1x10 + 2x9 + 1x8 + 1x7 / 5)
Sometimes:	7.00	(4x8 + 1x7 + 1x5 / 4)
Often:	7.00	(1x7 / 1)

No prosthesis users noted that they ‘Never’ had delayed response from their myoelectric hand within those surveyed in phase 2. The majority of those surveyed noted that

they ‘Rarely’ had a delayed response from their myoelectric hand, but 40% had a delayed response ‘Sometimes’ and 1 had a delayed response ‘Often’. There was a clear difference between the socket tightness rating for those users who noted that they ‘Rarely’ had delayed myoelectric hand response (8.6 average) and those that encountered these problems ‘Sometimes’ or ‘Often’ (7.0 average).

3.5.5.4 *Unwanted hand response versus electrode tightness rating*

The following data correlates to users’ response to the question**: *“Does the prehensor / hand ever activate on its own when you don’t want it to?”*** matched against user’s ratings for electrode tightness.

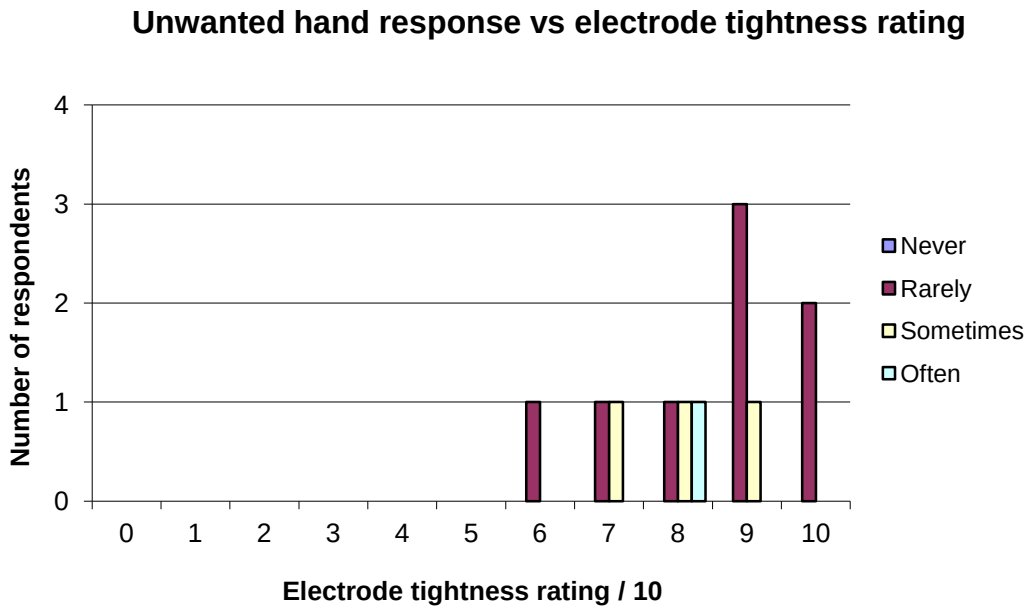


Fig 3.12(b): Unwan**t**ed myoelectric hand response versus electrode tightness

Average Electrode tightness rating for appropriate response regarding Unwanted hand response:

Never:	-	
Rarely:	9.20	(2x10 + 2x9 + 1x8 / 5)
Sometimes:	7.50	(1x9 + 2x8 + 2x7 + 1x6 / 6)
Often:	7.00	(1x7 / 1)

No user again noted that they ‘Never’ had unwanted hand response. Most users again noted that they ‘Sometimes’ had unwanted response from their myoelectric hand, and this time there was a significant difference noted in tightness ratings for the electrodes between ‘Rarely’

and ‘Sometimes’. This difference was seen to 1.70 (9.20-7.50) on average between these noted responses.

3.5.6 *Section D: Reasons for prosthesis rejection*

No users rejected their myoelectric prostheses from those surveyed in phase 2.

3.5.7 *Section C results: Perceived tightness versus prehensor response-combined*

3.5.7.1 *Delayed hand response versus socket tightness rating*

The following data correlates to users’ response to the question**: *“Does the prehensor / hand ever fail to activate when you want it to?”*** matched against user’s ratings for socket tightness.

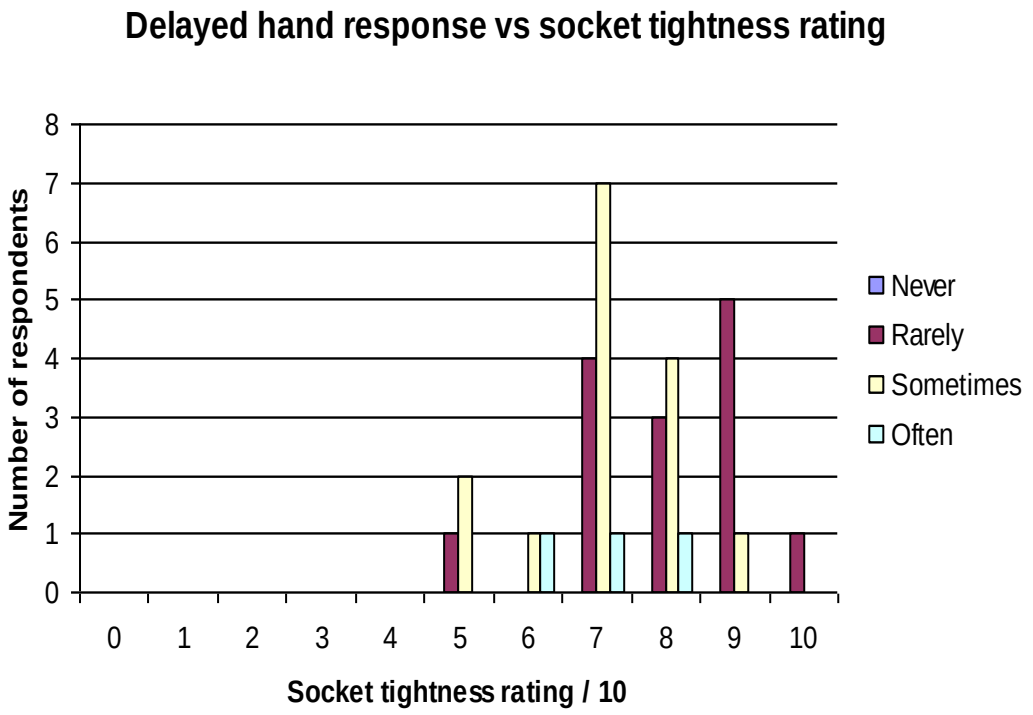


Fig 3.13(a): Delayed myoelectric hand response versus socket tightness

Average Socket tightness rating for appropriate response regarding delayed hand response:

Never:	9.00	(1x9 / 1)
Rarely:	8.00	(1x10 + 5x9 + 3x8 + 4x7 + 1x5 / 14)
Sometimes:	6.93	(4x8 + 7x7 + 1x6 + 2x5 / 14)
Often:	7.00	(1x8 + 1x7 + 1x6 / 3)

Combining the results from both phases, it can be seen that there is an almost symmetrical split between users noting delayed myoelectric hand response as either 'Sometimes' or 'Rarely'. Both of these responses are the largest, by some considerable margin (14 users each). Only 1 user out of 32 noted that they 'Never' had a delayed response from their myoelectric hand, whilst 3 (9%) noted that they 'Often' encountered a delayed response from their myoelectric hand.

Although the correlation between a higher socket tightness rating and improved hand response appears to be consistent between responses for 'Never', Rarely' and 'Sometimes', the average tightness rating appears to plateau at around 7 out of 10, with no significant difference between the noted delayed responses 'Sometimes' and 'Often'.

3.5.7.2 *Delayed hand response versus electrode tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever activate on its own when you don't want it to?"*** matched against user's ratings for electrode tightness (see **figure 3.14b, overleaf**).

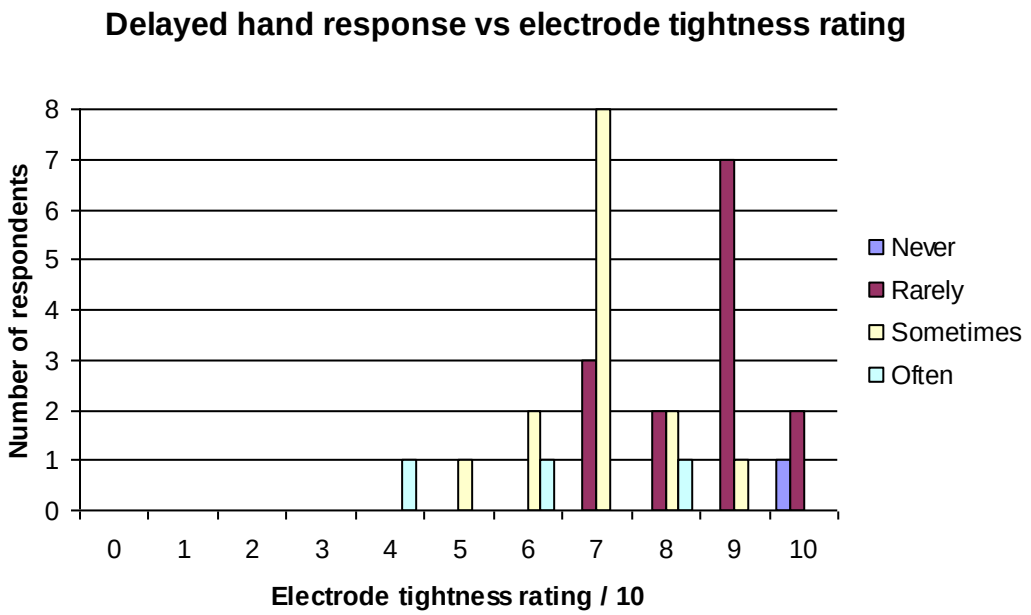


Fig 3.13(b): Delayed myoelectric hand response versus electrode tightness

Average Electrode tightness for appropriate response regarding delayed hand response:

Never:	10.00	(1x10 / 1)
Rarely:	8.57	(2x10 + 7x9 + 2x8 + 3x7 / 14)
Sometimes:	7.00	(1x9 + 2x8 + 8x7 + 2x6 + 1x5 / 14)
Often:	6.00	(1x8 + 1x6 + 1x4 / 3)

A much clearer distinction was seen with regard to the correlation between the responsiveness of the myoelectric hand and the electrode tightness rating than was evident previously with regard to the socket tightness rating. Here, it can be noted that the tightness ratings fall gradually as the responsiveness decreases from the myoelectric hand, with the lowest average electrode tightness being distinctly associated with users who noted that delayed response from their myoelectric hand occurred 'Often'. However, even here it can be noted that the difference between the tightness ratings between each response is smallest between 'Sometimes' and 'Often' (a difference of 1.0, compared to a difference of ~ 1.5 between the two other responses).

3.5.7.3 *Unwanted hand response versus socket tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever activate on its own when you don't want it to?"*** matched against user's ratings for socket tightness.

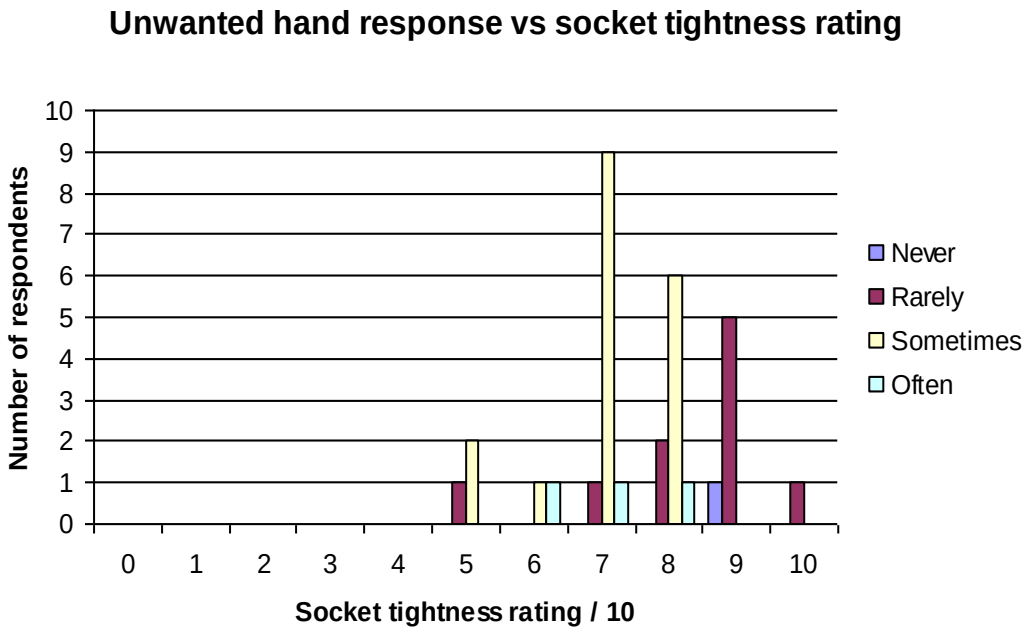


Fig 3.14(a): Unwanted myoelectric hand response versus socket tightness

Average Socket tightness for appropriate response regarding Unwanted hand response:

Never:	9.00	(1x9 / 1)
Rarely:	8.30	(1x10 + 5x9 + 2x8 + 1x7 + 1x5 / 10)
Sometimes:	7.05	(6x8 + 9x7 + 1x6 + 2x5 / 18)
Often:	7.00	(1x8 + 1x7 + 1x6 / 3)

Unwanted hand response appeared to occur more frequently than delayed hand response, with 18 users noting that unwanted hand response occurred 'Sometimes'. Only 11 users, ~ 35%, noted that unwanted hand responses happened 'Rarely' or 'Never'. However, with regard to the socket tightness rating for each noted hand response, the difference in the average tightness rating was only 2.0 between users who noted that unwanted hand responses occurred 'Never' and those encountered these 'Often'.

3.5.7.4 *Unwanted hand response versus electrode tightness rating*

The following data correlates to users' response to the question**: *"Does the prehensor / hand ever activate on its own when you don't want it to?"*** matched against user's ratings for electrode tightness.

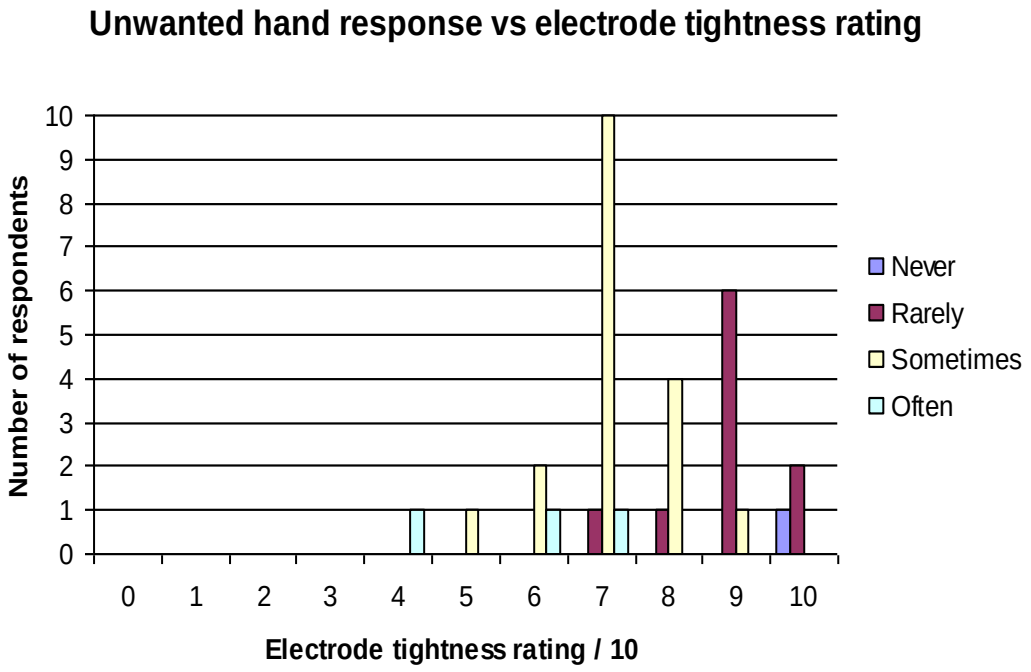


Fig 3.14(b): Unwanted myoelectric hand response versus electrode tightness

Average Electrode tightness for appropriate response regarding poor hand response:

Never:	10.00	(1x10 / 1)
Rarely:	8.90	(2x10 + 6x9 + 1x8 + 1x7 / 14)
Sometimes:	7.72	(1x9 + 4x8 + 10x7 + 2x6 + 1x5 / 18)
Often:	5.67	(1x7 + 1x6 + 1x4 / 3)

The average tightness ratings for the electrodes were significantly larger for unwanted hand response than the corresponding socket tightness ratings. Here, the difference in average electrode tightness ratings between those users that noted unwanted hand response 'Rarely' and those that noted it 'Often' was over twice as much (4.33, compared with the difference of 2.00 as noted in 3.15(b)). Interestingly, the largest difference between tightness ratings for electrode tightness versus unwanted response can be noted between the average tightness ratings for 'Sometimes' and 'Often', a difference of 2.05, more than that noted between the whole range of responses for socket tightness.

3.5.8 *Section D: Reasons for prosthesis rejection-combined*

No users rejected their myoelectric prostheses from those surveyed in either phase.

3.6 *Statistical analysis*

For the statistical analysis purposes of this study, two separate tests were conducted, using the SPSS statistical programme from IBM. The first examined the distribution of the perceived tightness ratings from all the users involved within the study, correlated against the response of the prehensor in each case. Since the numbers involved were all relatively small in statistical terms, and the data was non-parametric, an independent-samples Kruksall-Wallis test was applied to the data. The second analysis identified the distribution of the median tightness ratings within each group of prehensor response options. In this, case an independent samples median test was used.

Table 3.2 below identifies each area of prehensor response, and links these with the socket and electrode tightness ratings with respect to the options that were available to the respondents. The statistical significance for each of the tests as named is expressed as a figure within each of the respective columns.

The Null hypothesis for each test is:

Kruksall Wallis: The distribution of Socket / Electrode tightness is the same across each category of prehensor response.

Median test: The medians of Socket / Electrode tightness are the same across each category of prehensor response.

Analysis	Option variable	Kruksall-Wallis Significance	Median Test Significance	Decision at p=0.0025
Delayed response	Socket tightness	0.176	0.049	Retain
	Electrode tightness	0.015	0.002	Reject
Unwanted response	Socket tightness	0.074	0.016	Retain
	Electrode tightness	0.003	0.000	Reject

Table 3.2: Statistical analysis of socket and electrode tightness vs prehensor response

3.7 *Discussion*

The prosthesis usage patterns and generic data noted within this study correlate reasonably well with those conducted over the last 25 years (6). Body-powered prostheses appear to be used more infrequently, although it should be remembered that only 30% of the users surveyed had access to a body-powered prosthesis (**figure(s) 3.3**). This contrasts with the data provided by Ritchie et al (2011), who stated that body-powered prostheses were the most commonly used functional prosthesis (45).

Other factors may have influenced these results; the survey was only sent to myoelectric users, not all prosthesis users. Of those that did have access to both functional types, the body-powered was considered to be the most effective functionally (**figure 3.5**). The most useful prosthesis overall was the myoelectric prosthesis, with 69% of those surveyed identifying this as the best overall prosthesis (**figure 3.6c**). This fact is also reflected in the high

number of hours of daily usage that myoelectric prosthesis users attain with their prostheses (**figure 3.8c**).

Maintaining appearance and achieving cosmesis from the prosthesis is clearly important to prosthesis users (47). An upper limb prosthesis is harder to conceal than a lower limb prosthesis under clothing, the making appearance of the prosthesis more important to the user (2). Social inclusion is very important with regard to society and image, and getting back to employment and generally 'fitting in' are key aspects with regard to successful rehabilitation (237). The importance of cosmesis and the influence of technology and the interpretation of the term 'bionic' could all influence prosthesis choice and usage, providing more impetus to myoelectric prosthesis usage in some cases (6). In terms of pure function, it would appear that the myoelectric prosthesis is still some way short of the body-powered type.

This study shows that cosmetic prostheses and myoelectric prostheses offer almost symmetrical overall usage patterns, thereby indicating a significant correlation between these two types of prostheses. Comparing the usage of the body powered prosthesis and the myoelectric prosthesis, it is clear that there are major differences between the usages afforded to both types. Where the myoelectric prosthesis is worn comfortably in social environments, the body-powered prosthesis is not, a clear indicator of its poor appearance and social stigma (47). By contrast, for outdoor work, the body-powered prosthesis comes into its own (238). However, it should be remembered that using a body-powered prosthesis is not always easy to master, and of course it includes the disadvantages recorded earlier within **chapter 2** (120**)**. Nevertheless, for functional, daily living activities, it appears that this prosthesis despite its simple design can still afford the best functional outcomes (4, 6).

Although the questionnaire developed for distribution during phase 2 was sent to potential prosthesis users at all levels of upper limb absence, only transradial users responded. Usage rates for myoelectric prostheses amongst other levels of limb absence, particularly more proximal levels, are generally lower (16, 147). However, no users at either the transhumeral level or even the wrist disarticulation level of limb absence are a little surprising; some studies have detailed these cases at length as being reasonably proficient users of myoelectric prostheses (8, 118).

Contrasting the results relating to the tightness of the socket fit illustrates clear trends that are apparent with each area, between both distribution phases (see **table 3.2**). The link between delayed hand or prehensor response and socket and electrode tightness appears to be slightly less significant than the proportional link between unwanted hand or prehensor response and socket and electrode tightness, particularly at lower 'p' values. In addition, there is clearly a more significant link between electrode tightness and hand or prehensor response, than that between socket tightness and hand or prehensor response.

Clinicians agree that achieving the best socket fit is the most important factor for successful prosthesis usage (3, 23). However, the definition of 'best fit' is often subjective, with many prosthesis users favouring socket fits that are clearly different to the prescribed 'norm' (4). In myoelectric prostheses, a tight socket would appear to be an obvious requirement; since the electrodes that rely on an intimate fit at all times with the residual limb are housed within the socket walls. Consequently, a tight socket should restrict any movement between the electrodes and the residual limb thereby reducing motion artefacts. However, common socket designs used for myoelectric prostheses are often simple variations of those used for other types of prostheses, e.g. cosmetic prostheses, which do not normally require such an intimate fit (239). As a result, a tight fit is not always easy to establish, and even when it is achieved, this may not satisfy the prosthesis user in terms of comfort (1, 23).

The unique requirements of the prosthesis user, together with variations in the presentation of the residual limb, mean that socket fit can vary, and this is borne out by the variation in the perceived tightness of socket fit inherent in the results. All the tables suggest a trend towards better prehensor operation for tighter socket fit and electrode contacts produce the optimum functional response in terms of prehensor activation, a fact also noted by Daly (2000) amongst others (34). However, this trend appears to be more significant where unwanted prehensor response is concerned (**figure 3.14a, 3.14b, table 3.2**) - there is less discernible difference when delayed prehensor response is considered (**figures 3.13a, 3.13b, table 3.2**). This is particularly relevant with respect to socket tightness, where the trend is only very slight, and certainly not statistically significant.

For delayed prehensor response, electrode tightness becomes more of a significant factor (**figure 3.14b**). However, no users stated that they 'Never' had a delayed myoelectric hand or prehensor response. Most users had either 'Rare' prehensor activation delay, or were

they prosthesis was subject to delayed activation ‘Sometimes’. In terms of socket fit, there was no discernible difference between delayed activation that occurred ‘Often’ and that that occurred ‘Sometimes’ (**figure 3.13a**). The relationship between the socket and the activation delay did not appear to be as relevant as the relationship between the tightness of the electrodes and delayed activation.

The correlation between myoelectric hand and prehensor response and socket tightness is more clearly evident for unwanted hand or prehensor activation, i.e. from the potential impact of motion artefacts. For socket tightness, visual assessment of **figure 3.14a** illustrates a grouping of prosthesis users who had unwanted hand or prehensor activation ‘Sometimes’ at a lower tightness rating than others who ‘Rarely’ had unwanted activation. This becomes even more evident in **figure 3.14b**, which illustrates the correlation between electrode tightness and hand or prehensor response. It can be noted here that there is a clear, statically significant relationship between electrode tightness and unwanted prehensor activation.

The results suggest that a tight socket does not necessarily guarantee a secure contact between the electrodes and the skin of the residuum. Furthermore, as well as overall security, the electrode should have equal pressure maintained over its entire length if disturbance free operation is to be achieved (39). These results could also be linked to the condition of the myoelectric system and the course of repair and refurbishment administered. Some prosthesis users attend clinics more frequently than others and a poorly maintained myoelectric system will not provide optimum control (4, 240).

Methods for enhancing electrode contacts between the residuum and the electrode have included the use of roll-on silicone sockets, specifically designed to increase socket suspension and lack of motion, which have generally improved signal uptake and prosthesis control (33-35). Nevertheless, difficulties remain for upper limb prosthesis users with regard to donning these roll-on sockets, and problems with perspiration and skin care are also factors in their usage and general uptake (212, 213). Detachment of the electrode from the skin will lead to motion artefacts and unwanted activation of the prehensor, as well as failing to provide a basis for myoelectric signal transmission (39, 40). The results from this study suggest that unwanted prehensor activation and a failure to activate the prehensor when required are both affected by socket and electrode variations with regard to the tightness of fitting, although electrode tightness is apparently more of factor in this.

Socket volume matching and residual limb growth also provide challenges with respect to paediatric socket fitting. Children are often prescribed myoelectric prostheses, primarily because they are inherently quick at learning new techniques, and because of the cosmetic and technological appeal that myoelectric prostheses offer both them and their parents (6, 21, 52, 235). However, continual residual limb growth during childhood will limit the provision of an optimum socket fit at all times, thus potentially limiting the effectiveness of the myoelectric system (124, 149). With this in mind, it is feasible to suggest that a localised system of adjustment for the electrode housings and contacts may be more practical for signal acquisition than numerous remakes of the prosthetic socket (124).

Although myoelectric prostheses are often prescribed for children, placing the electrodes on the residual limb in the most suitable position, and achieving a signal of usable strength, is a challenge for Prosthetists, bearing in mind both the small residuum and the variable willingness of young children to conform to basic instructions (222). The electrode location is very much trial and error; the effect of poor location, or opting for myoelectric control without the necessary signal development within the muscle, may ultimately lead to premature rejection of the prosthesis or at least some disquiet regarding the functionality of the prosthesis (214, 222). Nevertheless, the myoelectric prosthesis is still very much favoured by parents, as it is seen as the most modern and therefore best option for their child (6, 222). Therefore, if any localised system could be devised that enables electrodes to be secured without incurring the need for a tight fitting socket, then sockets for myoelectric prostheses for children would be a key recipient.

Clearly, virtually all of the myoelectric prosthesis users surveyed (96%) had at least some degree of prehensor or hand interruption during daily prosthesis usage. The most significant statistical feature of the results appears to be the greater degree of correlation between myoelectric hand or prehensor response and electrode, rather than socket, contact (see **table 3.2**). Although it may be assumed that socket and electrode tightness are intrinsically linked, these results suggest otherwise, at least at lower ‘p’ values. Pursuing a device therefore that improves local electrode contact, rather than overall socket fit, could prove useful, particularly considering the nature of some of the residual limbs, which may fluctuate in volume due to growth, atrophy or overall weight change.

3.8 *Limitations and potential errors*

With any questionnaire, there is always an element of subjectivity with regard to the results, and clearly this questionnaire would be no exception, particularly with regard to the perception of socket and electrode tightness. Furthermore, the differences in the acquisition of the values associated with these sets of data between the two phases may have also led to some variations, potentially, at least, within the combined results data set. The relatively small response rate was slightly disappointing, and it is hard to determine the reasons for this. It may have been the case, for example, that non-respondents didn't reply because they were either very happy with, or by complete contrast no longer users of, their myoelectric prostheses. A follow-up study for those non-respondents would have been useful, but the issue of respondent confidentiality, necessary within the ethical remit of the questionnaire, made this course of action unobtainable. In addition, the mechanical reliability of the myoelectric prosthesis was not available for scrutiny. Despite these limitations, the very significant set of statistical results, particularly with regard to the link between electrode tightness and prehensor response, does however appear to make further study a viable proposition.

3.8 *Chapter summary*

Achieving good operational control of the prosthesis demands both an ability by the user to operate the myoelectric hand or prehensor when they wish, and also that no 'false' operation occurs when they require the hand or prehensor to be inactive. Overall control is clearly reliant on both of these factors. These results demonstrate that socket fit and its tightness correlates more distinctly with unwanted hand or prehensor activation, rather than delayed hand or prehensor response. Electrode fit and its tightness is more clearly related to both activation disruptions, but again this relationship becomes more distinct when unwanted activation is considered. Anecdotal evidence has suggested that some prosthesis users employ the electrodes within their sockets as switches, and actually use the motion artifacts created by movements between the skin and the electrode surface to activate the hand or prehensor. The results here suggest that this could be a factor in the relative differences between delayed and unwanted activation levels, particularly with respect to socket fit.

Despite these considerations, an intimate socket fit is important in virtually all prostheses, and myoelectric prostheses are no exception to this rule (1, 23). However, other factors such as volume changes within the residual limb, a change in shape of the residual limb associated with muscle contraction and the general design of the socket make maintaining

secure contact at all times particularly difficult (1, 23, 34). This survey has shown that close fitting sockets and close fitting electrode contacts are not always intrinsically linked, and therefore it may be possible to derive an electrode housing that could singularly resolve the myoelectric contact requirements, thus allowing socket variations to exist when required. This could preclude the requirement to use roll-on sockets, particularly for children with growing residual limbs which will be difficult to maintain a consistent tightness of fit. In addition, more proximal levels of limb absence that inherently consist of sockets that are less intimately fitting than the transradial sockets may benefit from locally adjustable electrodes that may maintain electrode security without necessitating a complete change to the design of the socket.

The consistently high usage rates exhibited by prosthesis users involved in this study suggests that myoelectric prostheses are worn as much for their cosmesis as for their functional value. The intermittent functional response illustrated by some of the myoelectric prostheses appears to have little effect on their daily usage. Although some of the users here may still wear their myoelectric prostheses despite the intermittent response of the hand, previous studies have shown that this is a problem for myoelectric users and may eventually lead to prosthesis abandonment. As with all prostheses, upper limb prostheses must offer a higher benefit versus cost ratio for the prosthesis user. In other words, the prosthesis user must see an overall benefit in terms of the factors as stated, such as function, cosmesis and comfort. It may be that this benefit ratio is still satisfactory, even with a relatively ineffective or intermittent functional response. However, this should not preclude the adaptation and functional improvement of current myoelectric prostheses.

The discrepancy noted here between the relevance of the electrode contact tightness and overall socket tightness is clearly of interest to this thesis. Therefore, the next chapter examines user’s myoelectric prosthesis functionality when electrode contact conditions are altered, but the socket remains the same. So far, the study has only involved the use of survey questions. To gain a greater insight into the impact of electrode contact, we need to employ functionality assessments that can accurately measure what may be achieved using different contact methods.

Chapter 4:
Assessing myoelectric prosthesis functionality using various electrode interface conditions: a pilot study

4.1 *Introduction*

The preceding chapters have identified that electrodes housed within the prosthetic socket in the standard arrangement may not always be in constant intimate contact with the surface of the residual limb during prosthesis usage. Current socket designs do not enclose the residual limb with sufficient intimacy to completely restrict movements between the inner wall of the socket and the skin of the residual limb. As a result, there is the potential for the electrode contacts which acquire the myoelectric signal to become detached from or move with respect to the surface of the skin during prosthesis use.

Chapter 3 demonstrated that a perceived less intimate electrode-to-skin contact by users of upper limb myoelectric prostheses was directly related to false activation of the prehensor, and that false signals generated from electrodes and sockets which were loose fitting were more likely to affect prehensor control. However, it was also apparent that the perception of socket tightness was not necessarily the same as electrode tightness, and that socket tightness did not correlate as distinctly with myoelectric hand or prehensor response as electrode tightness.

However, there has been little research to date which has investigated the link between the intimacy of socket-housed electrode-skin contact and its potential effect on myoelectric signal uptake and prosthesis response and prosthesis functionality. This chapter therefore focused on an investigation which examined how different methods of securing the electrode to the prosthetic socket or residual limb may affect the production of motion artefacts and the resultant functionality of myoelectric transradial prostheses.

The hypothesis was that the provision of an intimate contact between the electrode-to-skin interface using local contact enhancement within the prosthetic socket would restrict the production of unwanted motion artefacts and thereby improve prehensor control and prosthesis functionality. Different electrode contact scenarios were therefore identified and assessed with regards to their efficacy in providing prosthesis functionality using sockets which housed the electrodes. Primarily, it was the intention to establish if current practices

with regards to electrode housing arrangements are the most appropriate for myoelectric signal acquisition and whether changes to these practices could improve this signal acquisition and thereby increase prosthesis functionality and user capability.

In order to obviate the potential shortcomings inherent in current myoelectric prosthesis design and electrode security, it was first necessary to investigate and examine current best practice for surface myoelectric signal acquisition in more detail, and to contrast this best practice with current systems that are commonly used in clinical practice within a standard myoelectric prosthetic socket. The following section outlines the principles of selection of electrode positioning and signal acquisition recommended in the literature and how these recommendations may or may not be applied within upper limb prostheses and currently available myoelectric control systems.

4.2 *Myoelectric signal acquisition: a review of recognised best practice*

The acquisition of myoelectric signals is not restricted to prosthesis control. The SENIAM group have published a number of recommendations for signal acquisition (170). These recommendations are listed in **table 4.1** and are contrasted to current prosthetic practice.

Electrode Parameter	SENIAM recommendations	Standard Myoelectric Electrode	Compliance
Shape	The SENIAM recommendations for sensors are restricted to bipolar sensors only. 'Electrode shape' is defined as the shape of the conductive area of the SEMG electrodes. SENIAM has found no clear and objective criteria for recommendations for electrode shape. SEMG users should clearly indicate the type, manufacture and shape of the electrodes used.	Various shapes have been employed; the standard types are circular or square.	**YES**
Size	The SENIAM recommendations for sensors restrict to bipolar sensors only. 'Electrode size' is defined as the size of the surface of the conductive area of a SEMG electrode. SENIAM recommends that the size of the electrodes in the direction of the muscle fibres is max. 10mm.	The size of the electrodes in the direction of the muscle fibres is <10mm.	**YES**
Inter-electrode relationship	The SENIAM recommendations for sensors restrict to bipolar sensors only. 'Inter electrode distance' is defined as the centre to centre distance between the conductive areas of 2 bipolar electrodes. SENIAM recommends applying the bipolar SEMG electrodes around the	The distance between the bipolar diodes on the standard myoelectric electrode is ~20mm.	**YES**

	recommended sensor location with an inter electrode distance of 20 mm. When bipolar electrodes are being applied on relatively small muscles the inter electrode distance should not exceed 1/4 of the muscle fibre length. In this way unstable recordings, due to tendon and motor endplate effects can be avoided.		
Material	SENIAM recommends the use of pre-gelled Silver / Silver chloride electrodes	Electrodes are normally made from stainless steel, with no gel involved on application.	**NO**
Construction	SENIAM recommends a construction with fixed inter electrode distance, built from light weight material. *Cables* need to be fixed using (double sided) tape or elastic band in such a manner that pulling artefacts can be avoided.	The electrodes and cables are located within a prosthetic socket that is not intrinsically fixed to the residual limb.	**NO**
Skin Preparation	The SENIAM recommendations for skin preparation recommend shaving the patient if the skin surface at which the electrodes have to be placed is covered with hair. The next step is to clean the skin with alcohol and allow the alcohol to vaporise so that the skin will be dry before the electrodes will be placed.	The skin is not normally prepared prior to donning of the myoelectric prosthesis	**NO**
Location	SENIAM has developed recommendations for sensor locations on the following arm or hand muscles: • Biceps Brachii (short and long head) • Triceps Brachii (lateral head)	In the transradial amputation, the muscles used for signal acquisition are the remains of the wrist flexors and wrist extensors	**NO**

	• Triceps Brachii (long head) • Abductor policis brevis	For the less common transhumeral amputation, the Biceps Brachii (short and long head) Triceps Brachii (lateral head) Triceps Brachii (long head) are all employed for signal acquisition.	**YES**
Placement / Fixation	The SENIAM recommendations for electrode placement and fixation consist of recommendations for the: <u>Orientation of electrodes</u> 'Electrode orientation' is defined as the position of the line between the 2 bipolar electrodes with respect to the direction of the muscle fibres. SENIAM recommends that the bipolar SEMG electrodes should be placed around the recommended sensor location with the orientation parallel to the muscle fibres. <u>Fixation on the skin</u> SENIAM recommends to use elastic band or (double sided) tape / rings for the fixation of the electrodes (construction) and cables to the skin in such a way that	<u>Orientation of electrodes</u> The electrodes are aligned parallel to the muscle fibres in the optimum position as determined by the Prosthetist. However, no adjustment to this position is possible once the electrodes are fixed within the socket. <u>Fixation on the skin</u> The electrodes are secured within the socket but not normally to the	**YES, with conditions** **NO**

	the electrodes are properly fixed to the skin, movement is not hindered and cables are not pulling the electrodes (construction). <u>Location of the reference electrode</u> Depending on the application SENIAM recommends to use the wrist, the proc. spin. of C7 or the ankle as the standard location of the reference electrode.	skin itself. <u>Location of the reference electrode</u> The reference electrode is located within the main housing of the electrode body	**NO**
Testing of the connection	SENIAM recommends a clinical test for each individual muscle. The clinical tests which are described are generally accepted muscle tests which guarantee (under normal circumstances) activity of the tested muscle. The clinical test has to be started from the starting posture described in the SENIAM recommendations for sensor locations and has to be performed according to the recommendations. The clinical tests described are not 'selective' contractions in which only the desired muscle is active and all other muscles are inactive.	The myoelectric assessment assesses muscle groups for transradial limb absence in multiple rather than individual muscles. At more proximal levels of limb absence, individual muscles are assessed.	**YES (Proximal levels)** **NO (Transradial)**

Table 4.1: SENIAM best practice recommendations for surface electrodes acquiring the myoelectric (EMG) signal (170)

There are a number of key areas where current myoelectric signal acquisition for prostheses differs from the SENIAM recommendations. The most notable of these is the electrode to skin contact arrangement, where the electrode in the myoelectric prosthesis is not adhered to the skin during signal acquisition as recommended by SENIAM (39, 40). The main reason for this is the fact that the myoelectric prosthesis is a self-contained unit, which must be capable of being donned and doffed, and the electrodes are housed within it (1, 23, 39, 72).

Comparing the SENIAM recommendations with standard myoelectric practice shows a clear distinction between the compatibility of the electrode structure, and the compatibility of the method of attachment with these directives. In terms of electrode structure, myoelectric practice is closely aligned to best practice, with electrode size, shape and inter-electrode distance all being within recommended boundaries. Semi-conductor technology has enabled the usage of small structures and systems that are appropriate for the dimensions of upper limb prostheses (241).

This is clearly not the case in terms of the methods employed at the electrode-skin interface in myoelectric prostheses. Some practices, such as the use of gel, may be particularly difficult to employ within myoelectric prostheses. Maintaining a stiff socket-residual limb interface and the problems with gel removal during donning and doffing, make the use of gel impractical with current prosthesis designs. However, there are discrepancies with respect to electrode attachment and security. Whereas best practice dictates adherence of the electrode to the skin, and the cables held onto the skin, in clinical practice anecdotal evidence suggest that the standard socket-housed electrodes are currently either held onto the skin via elastic bands, or plastic or felt washers, or not kept in secure contact at all.

The issue is therefore whether these changes compared to the SENIAM recommendations do significantly alter the signal uptake to a degree that compromises prosthesis functionality and usefulness. Key factors regarding the acquisition of the myoelectric signal should also be considered. The following review examines those factors that affect the acquisition of the myoelectric signal at the electrode-skin interface.

4.2.1 *Acquiring the myoelectric signal at the surface of the skin: a review*

In order for any control method to be successful, the control source must be accurately detected and measured; and myoelectric control is no exception to this rule (241). Surface myoelectric signal control is regarded as the most important method of control for electrically powered prostheses (242). However, despite the large numbers of studies investigating surface myoelectric signal acquisition, it is still poorly understood (241). Usage levels have been linked to a lack of prosthesis controllability, and are hence the reason why this is such an important focus for this study (242).

Problems with signal acquisition are related to the manner in which the signal is produced. Most current systems rely on amplitude coding of the signal, which inherently uses the signal peak value as the defining control source within a relatively simple 'on-off' threshold-type system (see also **chapter 2**) (242). However, the muscle signal pattern takes time to maximise, gradually increasing in amplitude as the muscle fibres which provide the signal are recruited in sequence (187). As a result, the myoelectric signal is not an-easily readable, single peak signal but is actually a compound and rather complex signal, which is difficult to break down into definable sub elements (243). Effectively, this means that the signal has a small time-delay until it reaches its peak and there is therefore a consequent, proportional time delay before the appropriate myoelectric hand function is engaged (242).

In addition, maintaining a secure interface between the electrode and the skin can be difficult within current designs for myoelectric prosthesis sockets, thereby creating problems for functional usage (207, 243). According to the SENIAM recommendations, the electrode should be secured to the skin for effective signal acquisition (170). If this is not achieved, then movements between the contact surfaces of the electrode and the skin of the residual limb may occur. Differential electrodes, as employed within myoelectric prostheses, are particularly susceptible to electrical discharge, due to differences in the impedance and surface conditions of the skin over very small intervals across its surface (170, 243). Even very slight movements can cause motion artifacts to be propagated, and can also create electrical noise, which will also interfere with the target signal (171).

Although a study performed by Hamdi et al in 2012 did comply with SENIAM recommendations by using electrodes adhered to the skin during investigative trials (69), in normal clinical prosthesis usage this does not occur (40). Ethical issues regarding the use of

these techniques have prevented their integration within clinical prostheses, although the use of invasive EMG acquisition has been shown to improve signal clarity (183).

The use of alcohol and other cleaning agents to reduce the impedance produced either by impurities and debris on the surface of the skin itself, plus the use of gel to improve conduction of the signal across the skin surface, has been shown to improve signal uptake at a range of signal frequencies (198, 242). This outermost layer of the skin, the stratum corneum, has a major impact on signal impedance at frequencies lower than 1000Hz, which is the target range for myoelectric signal acquisition (201). Impedance will also occur as a result of the tissue which separates the target muscle from the skin surface (69, 198). This impedance is increased along with signal noise in relation to the thickness of the tissue, and particularly where adipose tissue is present (198). Impedance is relevant to EMG transmission and acquisition, since it influences the amount of signal that can be acquired at the skins surface. Should this vary, particularly during muscle contraction, then it will hinder proprioceptive feedback with regard to the correlation between muscular contraction and output. Consequently, according to Kuiken et al (2003) this 'may pose considerable problems in the control of myoelectric prostheses' (164).

Since the tissue between the electrode and the target muscle is normally compliant, it could theoretically be displaced under pressure and therefore reduce the amount of tissue between the point of contact and the muscle beneath it. Applying contact pressure has been shown in the literature to improve signal acquisition, most markedly from a test condition of no pressure to relatively small, easily tolerable loads on the skin (171, 244). There is little increase from these small loads to much larger values, indicating that the tissue is easily displaced leading to relatively quick improvements in signal acquisition capability (244).

Other factors which have been shown to improve signal uptake include the use of electrolytic gel, which can improve peak signal values up to tenfold (164, 171). However, the use of gel, which lowers the coefficient of friction at the skin's surface, is incompatible with socket housed electrodes which may move in relation to the skin surface and therefore create motion artefacts.

The deficiencies noted in maintaining secure electrode-skin contact have been blamed for the failure to implement improved control systems, such as pattern recognition (200).

Pattern recognition uses specific EMG patterns learned by training a classifier and responding appropriately when these signals are reproduced. Although first noted in 1993 by Hudgins et al, this system has as yet has not been implemented within standard clinical myoelectric prostheses (4, 208).

Using the defined signal patterns from each muscle has also been examined by Al-Assaf and Al-Nashash (2005) (210). Each muscle possesses myoelectric signal patterns which can be identified and used as a control source; thereby potentially eliminating cross-talk between muscles. Assaf and Al-Nashash discovered a 5.1% error when 2 channels (electrode sites) were used. Using single-site systems increased the error values but was easier to process and classify for potential prosthesis operation (210). However, natural forearms were used, which would have provided clearer signals. In addition, the muscle location would have to be accurately targeted for this system to work, as the signal may acquire noise as it travels through other tissues, thereby lowering the effective amplitude before it reached the electrode (39, 164, 205).

A more complex control system, although potentially more able to deliver greater function, is even more reliant on a clear, controllable input signal and is therefore more prone to failure should the input signal be disrupted (39). The use of pattern recognition systems to mirror those employed within the natural arms control network represents an opportunity for more natural, improved upper limb control (39, 208). Pattern recognition would also complement the latest, most complex multifunctional hands and elbows, such as the Utah MIT dextrous hand, offering 16 degrees of freedom or the I-Limb (189). These multi-functional hands with numerous grip options afford the potential for greater dexterity but, at the point of writing, results suggest that they still fail to improve on the basic single-grip types of prosthetic hands (8). Improvements in prosthesis hardware can only be worthwhile if they lead to an increase in prosthesis function, something which may be restricted by other components within the myoelectric control system (153).

To alleviate the problems associated with electrode-to-skin contact, electrodes have been trialled which were implanted within the muscle tissues, although ethical approval and the willingness of individuals to undertake such procedures provides limitations to overall clinical usage. An implantable sensor was developed by Lichter et al (2010), but was not

tested on subjects (218). Instead, the sensor was immersed in a saline solution to mimic the conditions of implantation.

Other solutions to the problem of electrode-skin contact have focused on alternatives to the principle of signal acquisition as the control source. Mechano-myography (MMG) measures the transverse displacement of the skin over the contracting muscle, and has been presented as a viable alternative method of control by Silva et al (2005a, 2005b) (244, 245). MMG usage in this study enabled 71% and 88% control success rates for two subjects respectively, but the method of testing was not a standard, verifiable upper limb assessment technique (244). In addition, loading the prosthesis via an object held in the myoelectric hand was shown to cause vibration problems which had a negative impact on prosthesis controllability (245). However, an advantage of this system was the use of multiple sensors, negating the need for sensor accuracy in placement and position; unlike surface myoelectric signal acquisition which depends strongly on electrode location (183).

Identifying specific muscle firing patterns, and incorporating these into pattern recognition systems, can more easily be achieved using able-bodied subjects and natural forearms (31). However, transposing these patterns into controllable systems using patterns derived from muscles within residual limbs is difficult, since these will inherently be less clearly defined than those from the natural forearm, particularly those on residual limbs caused by congenital absence (73). The natural forearm muscles, particularly the wrist extensors, provide better control over a given myoelectrically-controlled task than those within a residual limb (69, 181). This difference is also magnified by the difficulty of the task, i.e. when the task becomes more challenging, the discrepancy between the results from the natural forearm and the residual limb increase (69).

4.2.1.1 *Review Summary*

The above analysis highlights the fact that although alternative signal acquisition techniques have been developed in recent years, the problem remains that they cannot be translated into viable systems with upper limb prosthetic sockets due to the reasons given above. It is therefore the case that there is a need to develop an alternative method of improving signal detection rates using currently available electrodes for prosthesis users. In order to do this, the intimacy of contact between the skin surface of the residual limb and the electrodes also needs to be improved. The following sections describe a study in which

different electrode test conditions were investigated within upper limb prostheses in order to provide a method of analysing different electrode arrangements within the prosthetic socket.

4.3 *Designation of appropriate test conditions*

Three test conditions were designed to give clear and definitive answers to the test question. Securing the electrodes directly onto the skin surface without them being subject to socket movements, (i.e. by not attaching them to the socket except via the mandatory leads), would clearly demonstrate if mutual movement between the skin and the electrode was influencing prosthesis functionality. It was therefore necessary to develop a way of attaching the electrodes to the skin independently from the prosthetic socket wall in an upper limb prosthesis whilst still being suitable for use within a working and viable prosthesis linked to a suitable, comparative functionality assessment.

In addition, the standard electrode housing arrangement in which the electrodes are fixed into position within an electrode housing that is manufactured into the prosthetic socket (as commonly used in clinical myoelectric prostheses), would also need to be used within the test protocol as the ‘control’ method. The positioning and location of the electrodes within the socket housing were obtained from the standard clinical casting and rectification practice used to produce standard transradial myoelectric sockets. This test condition would then closely reflect the normal levels of prosthesis control and functionality which may be expected by users of myoelectric prostheses currently being prescribed and fitted with upper limb prostheses.

A third test condition, involving the development of an innovative socket housing design, which would allow the intimacy of contact between the skin and the electrode within the prosthesis to be adjusted by the prosthesis user, was also employed. This arrangement would determine whether local adjustments to the electrode/residuum interface would produce a discernible and measurable functionality improvement for the myoelectric prosthesis user.

The null hypothesis was therefore that increasing the perceived intimacy of the contact and theoretically reducing motion between the electrode and skin surface within a transradial prosthetic socket will not result in enhanced prosthesis functionality.

4.4 *Methodology*

Prior to the commencement of the study, ethical approval was received from the appropriate United Kingdom NHS COREC ethical committee. Three volunteer transradial myoelectric prosthesis users were recruited for this study from prosthetic service centres within the North West of England, UK. Relevant ethical approval documents, together with a patient consent form, can be viewed in **Appendix B**-*Ethical approval and related documents.* Associated documents with this investigation also included a patient information sheet, patient consent form and an investigation protocol adapted from those available within **Appendix A-***Questionnaires and Questionnaire development* with alterations provided detailing the differences in the analysis regime.

The inclusion criteria were as follows:

- All subjects were transradial level of absence;
- No subjects had a history of skin conditions, allergies or pathologies which would obviate the application of localised loading to the skin surface;
- All subjects were able to provide informed consent;
- No subjects had a history of paraesthesia (lack of sensation) in the upper limb and all subjects exhibited muscle strengths and normal ranges of motion at the shoulder and elbow joints within the affected upper limb;
- All subjects were at or above the age of 18 years, and
- All subjects were familiar with and had experience of operating myoelectric prostheses.

The selection process for this study and for others conducted using prosthesis users in all other investigations within this thesis, is illustrated in **figure 4.1** (below):

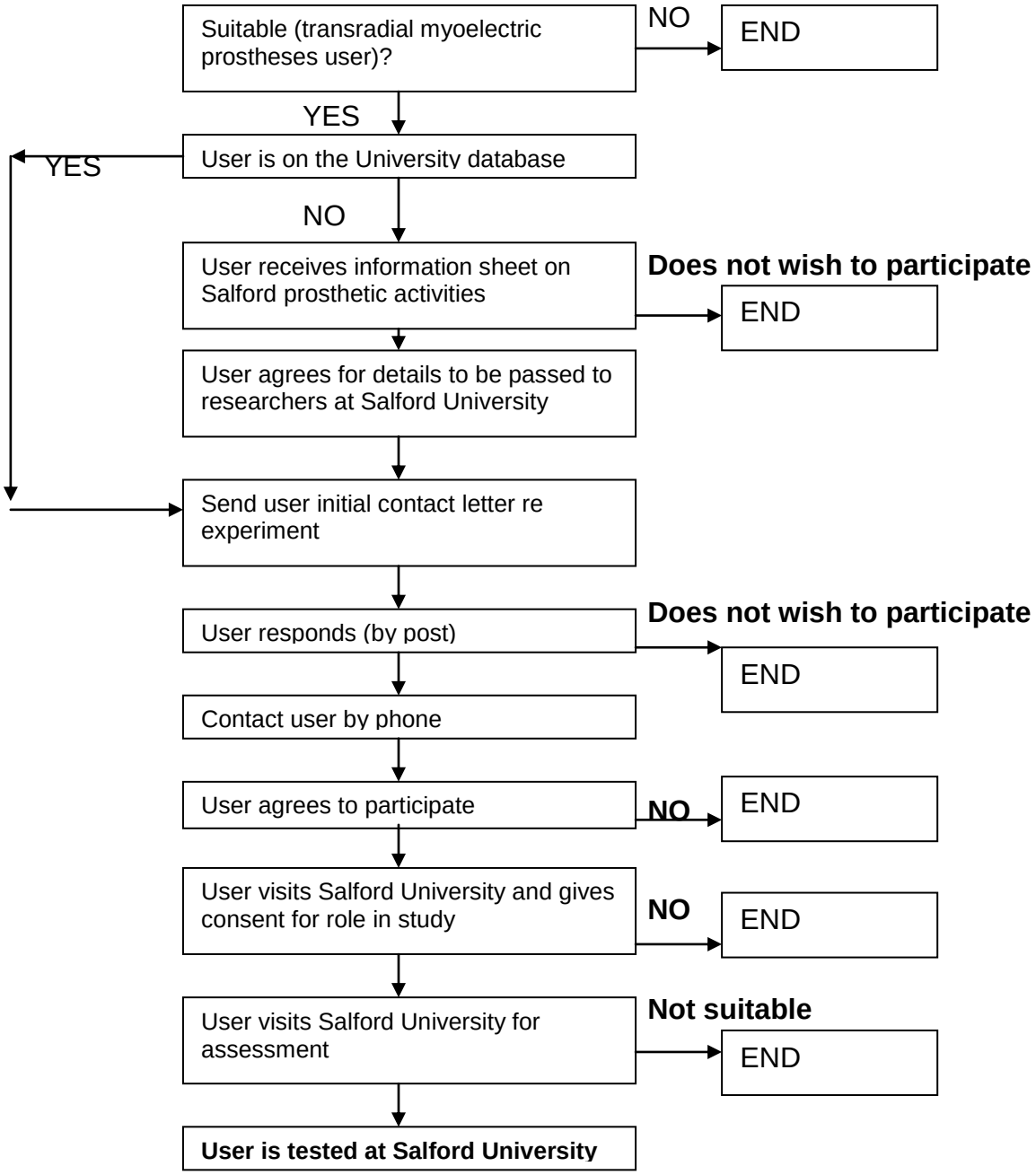


Figure 4.1: Selection and recruitment procedure

To enable an investigation regarding the relative levels of myoelectric prosthesis functionality produced from the three test conditions described in section 4.3, the following was required:

1. Suitable myoelectric prostheses which accurately reflected current standard upper limb myoelectric prosthetic prosthesis prescription;

2. Suitable socket types and electrode attachments which accurately reflected current standard prescription, together with bespoke designs to meet the requirements of the other two test conditions;
3. A previously validated and reliable method of assessing the functionality afforded by the three proposed test conditions which could accurately assess prosthesis functionality.

For accuracy and consistency, each of the test conditions had to be assessed within the same prosthetic socket, and whilst using the same prosthetic hardware (i.e. a myoelectric hand, myoelectric control system and prosthesis assembly). In **chapter 2**, the standard myoelectric prosthesis was described as an 'exoskeletal' design which incorporated a friction wrist unit (1, 23). For the purposes of this study, a similar exoskeletal prosthesis was designed for each socket test condition and the same myoelectric hand was used for each of the test conditions.

The assessment, casting and laminating methods employed for each of the socket types stated previously are illustrated within **Appendix C-** *clinical and technical methodologies***.**

The myoelectric hand and prosthesis arrangement utilised in this study is illustrated in **figure 4.4.** The myoelectric system employed included a 'Galateya NPF' – Reutov' model threshold-controlled myoelectric hand prehensor fitted with standard system-compatible electrodes using semi-rigid socket locaters, within a two-site, two-state control system. The myoelectric hand could be quickly and easily interchanged with a bespoke friction wrist unit, manufactured by the author to fit the respective screw attachment of the myoelectric hand which proved to be adequate in terms of hand positioning, retention and function.

Standardisation of component manufacture was employed to limit the effects of any external factors associated with using different myoelectric arrangements. Each test condition used the same electrodes, but each prosthetic socket for each volunteer prosthesis user was designed to accommodate three different test conditions of electrode placement within the same socket over the residual limb.

4.4.1 *Selection of appropriate test conditions*

Three test conditions were utilised to test the hypothesis. The standard method of electrode attachment within the prosthetic socket was used as part of the investigative methodology. In addition, there was a requirement to provide a method of attachment which would allow for the electrode to be securely fastened to the skin of the residual limb during prosthesis usage. This would enable the investigation to compare the functionality of a prosthesis that was potentially influenced by movements between the socket and the residual limb with that produced by a method of attachment which was not influenced by these movements. Additionally, a third method of electrode attachment was employed which would potentially improve the intimacy of the electrode / skin interface within the standard housing arrangement, but was still influenced by socket movements with respect to the residual limb which would occur during prosthesis use.

4.4.1.1 *Test condition 1: The standard housing method of attachment*

This method used electrodes fixed into suitable positions as determined by the Prosthetist during manufacture. This method will be examined more closely in **chapter 5**, but is also illustrated in **figure 4.5a**.

4.4.1.2 *Test condition 2: Best practice method-separated from socket*

To accurately assess the influence of the socket motion on prosthesis response and functionality, it was necessary to provide a comparable, separate method of electrode attachment which effectively removed the influence of relative motion between the electrode and the skin due to it being fixed into the socket walls. To achieve this, the electrode would have to be directly secured to the skin, yet still be able to operate a myoelectric prosthesis via connecting leads in the same way a standard housing arrangement would achieve this. In addition, the electrodes and the prosthesis used for both methods of assessment would have to be identical for an accurate relative prosthesis functionality assessment to be completed.

The most suitable method established to provide electrode detachment from the socket but still maintain the electrode on the residual limb over the contact sites was to secure the electrode surface to the skin of the residual limb in line with and directly underneath the position where the electrode would normally sit within the socket aperture in the standard arrangement. The electrode would not be able to be secured within the socket housing, since this clearly would leave it to vulnerable to the same movements as previously described.

Therefore, the semi-rigid attachments, used to secure the electrode within the standard housings, would not be necessary and would in fact obstruct the fitting of the electrode within the socket apertures.

Although current clinically available electrodes are manufactured by numerous prosthetic companies, the main structure of each is very similar. The signal acquisition and amplification electronics are located on a miniature circuit board, which in turn is located within a plastic housing.

The three electrode contacts which acquire the signal protrude from the housing by approximately 2mm. Since they must be maintained in close contact with the skin, any adherent material securing the electrodes to the skin must not cover these contacts. As these are the only parts of the electrode that normally contact the skin, adaptations had to be made to the electrode in order to successfully adhere it to the skin and prevent motion.

Two options were available which potentially enabled the electrode to be secured to the skin of the residual limb within the socket aperture whilst keeping the electrode contacts interfaced with the skin:

a) Building up the area of the electrode interfacing with the residual limb around the actual contact sites with ‘pelite’ polyethylene foam, thereby creating a flush surface between the contact faces and the ‘pelite’. Adherent material, such as strong double sided tape, could then be applied to the foam areas only, thereby securing the electrode to the skin. Adhesive was unsuitable, because it would have been difficult to remove and may have damaged the skin.

b) Attaching plastic tabs, or extensions, to each end of the electrode; these could be adhered to the skin and would again be flush with the signal-acquiring electrode contacts.

An initial trial of each of the above methods was undertaken on the author’s forearm using a bespoke socket design over suitable attachment points that corresponded closely to those used to acquire myoelectric signals. Consequently, a plaster cast was taken around the proximal forearm segment, and also around the elbow joint, in a fashion similar to the

standard ‘hybrid supracondylar’ cast used in standard UK clinical practice (see c**hapter 2**). From this cast, a supracondylar socket was manufactured, and apertures were created over the signal positions as deduced during the myoelectric assessment procedure.

Two electrodes were positioned within the socket and were subsequently connected to the myoelectric prehensor and control system. The connections and the components used were identical to those that would be employed within the prosthesis user investigation. An image of the author’s socket is shown in **figure 4.2** (below):

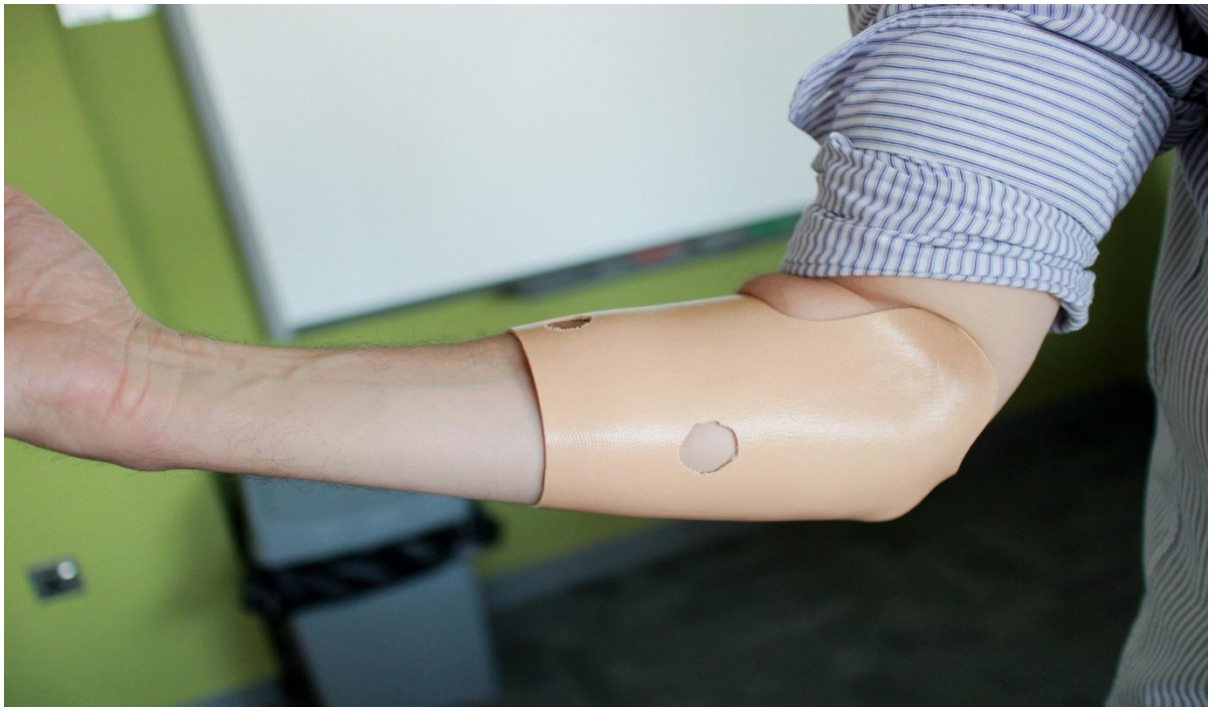


Figure 4.2: Bespoke socket on author’s forearm (author’s own image)

The author conducted two trials, lifting and releasing objects for a period of 5 minutes, with his natural hand whilst wearing the bespoke forearm on this side, using electrode attachment methods (a) and (b). It was found that the electrode maintained a secure fit to the skin of the forearm when fitted using option (b).

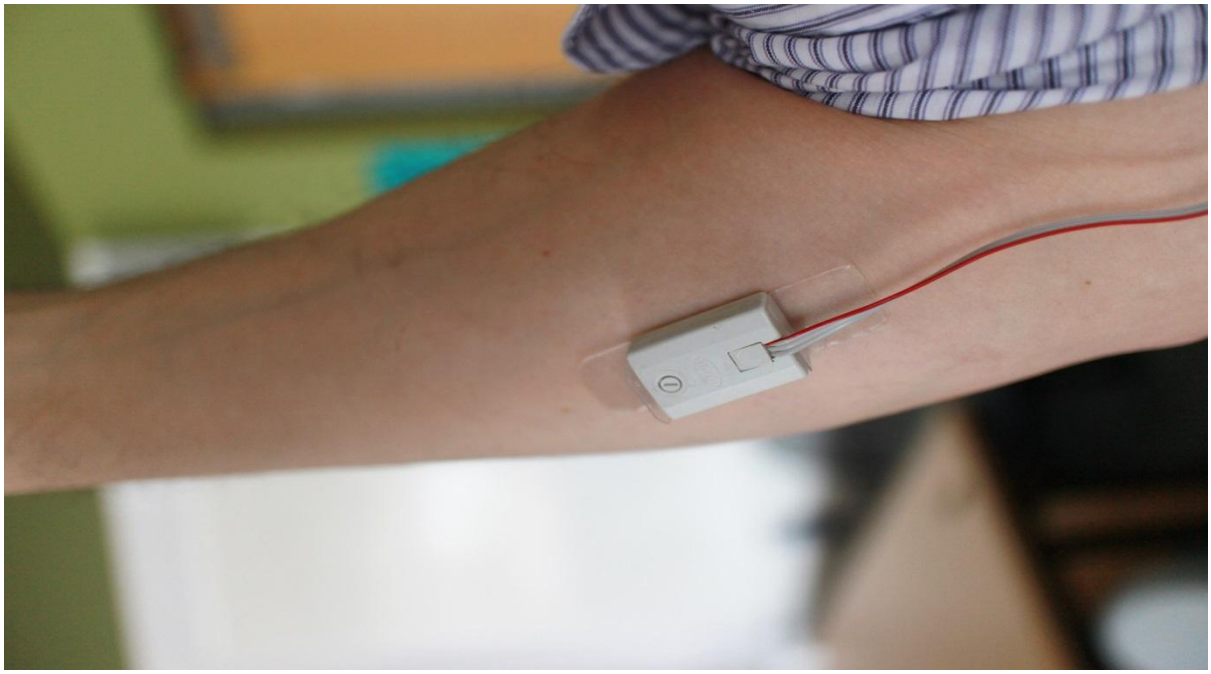


Figure 4.3: Electrode attached to author's forearm using option (b).

During trials of option (a) the electrode was dislodged three times during the trial procedure and therefore the control was not deemed to be effective. This option was therefore discarded. Option (b) was the chosen method of attachment, and is illustrated in **figure 4.3**. This was shown to retain the electrode onto the skin particularly effectively.

The electrode with the extension tabs was secured onto the skin within the apertures that had been created by the dummy housings during the lamination process; the adherent material found to be the most successful at adhering the tabs to the skin was extra-strong double–sided tape.

4.4.1.3 *Test Condition 3: The use of an external assistance device to improve contact*

A third method of attachment was trial-tested, which was designed to increase the intimacy of contact of the electrodes to the skin but this time using an adapted version of the standard electrode housing to secure the electrode within the socket but with an adaptation. Ideally, any additional attachment that increased electrode contact security during prosthesis usage would still need to enable the electrode to fit within the socket housing. Consequently, it was decided that the most suitable way to achieve this would be to use a screw-type plunger, housed above the electrode aperture, which could be adjusted to increase the level of pressure over the outer surface of the electrode housed within the socket. The plunger could

be unscrewed when necessary to enable the electrode to be positioned within, or removed from the socket housing with minimal disruption to the housing itself.

The initial plunger design consisted of a centrally-threaded aluminium strip, which was 10mm wide, 75mm long and 3mm deep, cranked into a position as shown in **figures 4.4 / 4.5**, and laminated within the socket walls directly above and around the electrode housing. The screw threaded-plunger consisted of a simple 4mm diameter 2cm long screw with an Allen-key head, which also consisted of a plastic disc, adhered to the distal end of the screw. The plastic disc increased the surface area of the screw plunger as it impacted on the electrode's outer surface, helping to maintain and improve a secure electrode contact attachment with the skin. The dimensions of the complete plunger design were calculated to allow for the electrode to be inserted within the socket housing relatively easily, but within a structure that would be easily adjusted and would not increase the overall weight of the socket to any significant degree.

The adjustability of the screw plunger allowed for the prosthesis user to select which level of contact was acceptable and comfortable during prosthesis wear. The plunger apparatus would not show the exact pressure between the electrode and the skin; however, it would secure the electrode to the skin more securely than when sited within the electrode housing without the plunger, and would enable the user to determine the level of comfort afforded during usage.

To conclude, the three test conditions therefore used for this study were:

1) Via standard housings, using standard semi-rigid locators inserted into socket holes created by the dummy electrodes (**test condition 1, figure 4.5a**).

2) Within a socket aperture, not connected to the socket but directly adhered to the skin using double sided tape positioned on plastic extensions built onto the ends of the electrodes (**test condition 2, figure 4.5b**).

3) Within the socket housing but with firmer contact pressure exerted onto the electrode/skin interface via an adjustable plunger located within the superior aspect of the electrode housing (**test condition 3, figure 4.5c**).

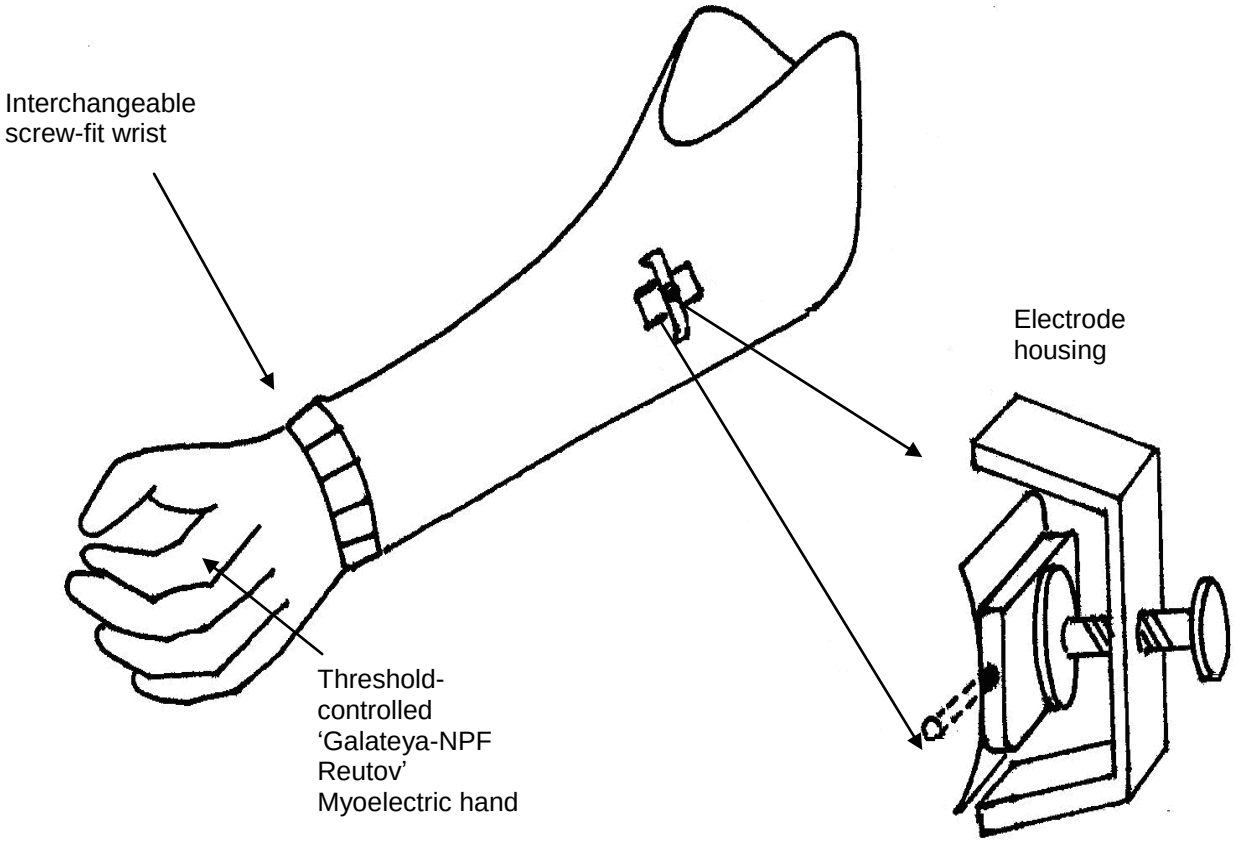


Figure 4.4: View of the myoelectric test prosthesis used in the study and an exploded view of the electrode housing. The electrodes were secured within the socket using standard flexible electrode arms, which slotted into holes created by dummy electrodes during the socket lamination procedure. **Test condition 1 simply utilised standard socket housing and standard semi-flexible electrode arms**. **Test** c**ondition 2** used electrodes with no flexible arm attachments but instead was secured to the skin using adhesive tape. **Test condition 3** used both the semi-flexible arms and the screw plunger apparatus as shown; the pressure of which was determined by the prosthesis user. (Author's own illustration)

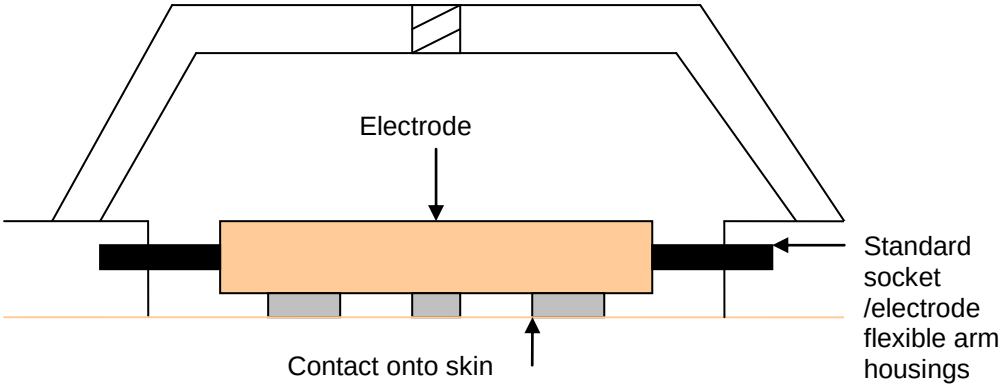


Figure 4.5a: Test condition 1-Electrode arrangement with standard housing

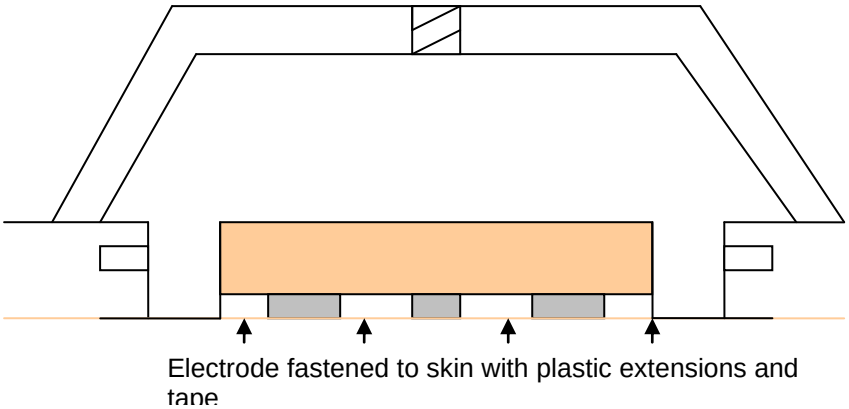


Figure 4.5 b: Test condition 2 - Electrode arrangement within aperture, fastened to skin

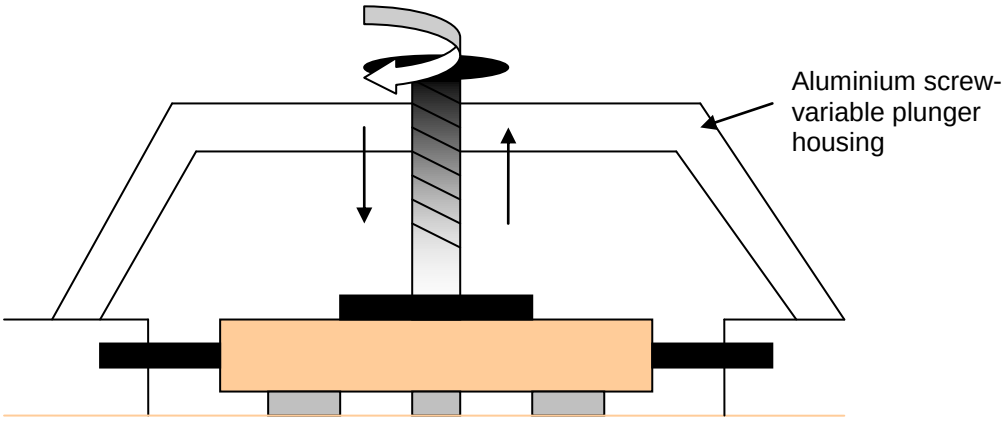


Figure 4.5c: Test condition 3 - electrode with plunger attachment located onto electrode but still using semi flexible lateral arms

The screw-variable plunger was located within an aluminium-alloy mounting, which was laminated into the socket around the electrode housing. The plunger could be retracted fully to allow the electrode to be located within the socket aperture for all three conditions.

In **test condition 1**, (where the electrode was located within the socket wall; **figure 4.5a**), there was potential for movement to occur between the electrode and the residuum during usage due to overall socket movement. Interface pressure would potentially vary depending on the intimacy of the prosthetic socket fit. In **test condition 2,** where the electrode was adhered to the skin within an aperture in the socket (**figure 4.5b**), electrode motion relative to the skin was minimised since the electrode was secured independently from the socket and interface pressure was stabilised. Finally, under condition 3, the electrode interfaced with the skin under intimate contact by means of the screw mechanism (**figure 4.5c**). This was designed to illustrate the effect of local adjustment upon the efficacy of the electrode/skin interface in improving myoelectric signal performance. Under **test condition 3**, the electrode was still potentially subject to motion between the socket and the residuum. The intention was to allow the plunger to secure the contact between the electrode and the skin over the length of the electrode, (which has been recommended in the literature to facilitate signal recognition and relaying) (40).

It was not the intention to measure interface pressure directly within this pilot study, but simply to utilise a comfortable interface pressure determined using feedback from the prosthesis user during the testing protocol.

Each prosthesis subject user was assessed for the optimal myoelectric signal position for each electrode site in accordance with recognised best and taught practice (39, 72) (see **Appendix C**-*Clinical and technical methodologies*). The selected system was two-site, two-state, which is the standard set up in most clinical myoelectric systems (196) (see also **chapter 2**).

Each socket was manufactured using a lamination process as outlined in **Appendix C**-*Clinical and technical methodologies.* An outer laminate was also attached to each of the sockets, which again was laminated in accordance with the design outlined in **figure 4.4** using Otto bock orthocryl laminate resin 617H17. The test prosthesis was able to house the electrode in all three of the test conditions, ensuring that any evident variances in control

were not influenced by factors unrelated to the testing conditions themselves **(**see test prosthesis, **figure 4.4**). Each socket fitting was adjusted to provide comfort for the prosthesis user. In addition, the gain or amplification setting of each electrode was adjusted to meet the specific requirements of each subject.

4.4.2 *Selecting the method of functionality assessment*

To accurately determine the relative effectiveness of each of the housing methods, a valid and reliable functionality assessment was required. Although there are many methods detailed in the literature to assess functionality, few assessments have demonstrated the capability to accurately determine the functionality of upper limb prostheses.

The two types of functionality assessment identified in **chapter 2** which are specifically suited to upper limb and myoelectric prosthesis assessment are the Assessment of Capacity for Myoelectric Control (ACMC) (84, 87) and the Southampton Hand Assessment Procedure (SHAP) (89). The SHAP functional assessment tool was chosen due to its portability and availability (89). At the time of the assessment, training for use with the ACMC was only available outside of the United Kingdom. In addition, the SHAP met all the relevant criteria for usage, and has been successfully implemented during a number of recent studies (91, 92).

The SHAP uses carefully-selected tests based around abstract object tasks, both heavy and light, and selected ADLs to provide a functionality score that may be compared to that of a fully-functioning natural hand. Each abstract object task relates to a specific grip pattern, and the SHAP assesses the contribution of each grip by recording the time taken for each grip-specific task. The times for these tasks are complemented by those achieved during a range of daily activities that have been selected to offer a balanced representation of all the grip types and common place daily activities that would normally be undertaken. The functionality score of the prosthesis being assessed is therefore acquired from the sum of the combined results of each of these assessments and is given as a score between 0-100 (89).

The overall functionality index score is based on a Euclidean squared distance metric, which enables a summative ‘as the crow flies’ distance to be calculated from the individual contributions of each of the grip patterns and hence produces a linear numerical scale. A score of 100 represents a fully-functioning natural hand, with consistent contributions from each of

the 6 grip patterns. The calculation methodology for the SHAP assessment is illustrated in **chapter 2**, section 2.5.4.

4.4.2.1 *The SHAP assessment tasks and activities*

The SHAP is supplied in kit form, and includes all the required items neatly packaged within a portable case. These items include the following:

1. A carry case, incorporating a zip, door handle and key in a lock within the upper case lid;
2. A simple timer with a large start/stop button and a reset capability;
3. A specially designed assessment tray, which has grooves and cut outs for each of the task objects;
4. Six abstract objects made from balsa or light wood;
5. Six abstract objects made from stainless steel, and
6. A button board, a standard cutlery knife, a perspex jug, a cardboard juice carton, some 'plasticine', a metal plate with a screw/arrow, a screwdriver, a perspex jar, and a tin can, which will be used to simulate the daily living activities.

The items included within the case lid detailed in point 1, along with those listed under point 6, make up the items used during the timed tests for ADLs. The SHAP is undertaken with the prosthesis user seated at a table with the tray/case sited on the table in front of them, and with the test/task objects and items within a comfortable reaching position.

4.4.2.2 *Abstract object tasks*

The testing procedure begins with the abstract object tasks, which require the prosthesis user to pick up and move abstract objects from one defined position within the assessment tray to another (see **figure 4.6**). There are two sets of six different abstract objects provided within the SHAP kit. Each set is identical in terms of the shapes and their dimensions, but one set is made from light balsa wood, and the other is made from a heavier metal alloy.

Each task, or movement of the abstract object, requires the employment of a specific grip type, and is timed using a timing device included within the SHAP assessment kit. The time taken to perform each task is recorded, and this indicates the subject's capability to

effectively reproduce and employ the related grip type. There are two specific cut-outs within the assessment tray that are specifically designed to securely accommodate each abstract object. The abstract object should be moved from one cut out to the other according to the specific designation of the task. Each task must be completed using **only** the prosthesis, with the timer also being started and stopped with the prosthetic hand only. The tasks undertaken in this functional test are listed below:

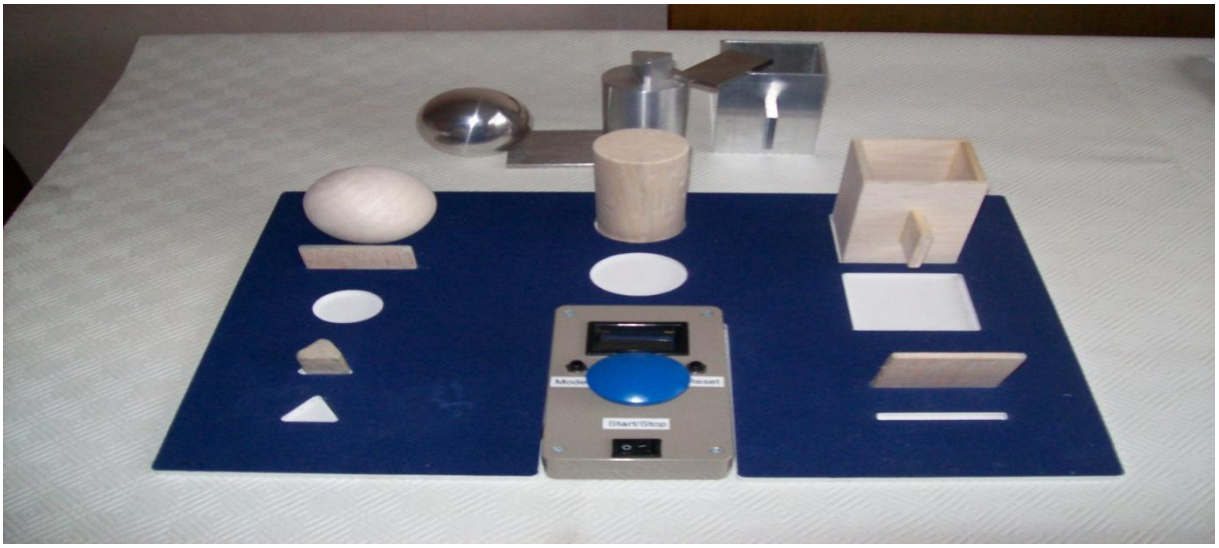


Figure 4.6: Abstract object shapes and the SHAP assessment tray (author's own image).

Task 1: The spherical grip: A sphere of 7 cm diameter is moved a distance of 7.5 cm between pre-formed cut outs within the assessment tray;

Task 2: The Tripod grip: A triangular cylinder with sides of 2 cm and height 2.5 cm is moved a distance of 4cm between pre-formed cut outs within the assessment tray;

Task 3: The Power grip: A cylinder of diameter of 5cm diameter and height 10 cm is moved a distance of 6.5cm between pre-formed cut outs within the assessment tray;

Task 4: The Lateral grip: A hollow square cylinder of thickness 0.5cm, sides of 6 cm x 6 cm and a height of 10cm is moved a distance of 7cm between pre-formed cut outs within the assessment tray;

Task 5: The Tip grip: An oblong piece 6cm x 3 cm and 0.5 cm thick is moved a distance of 3cm between pre-formed cut outs within the assessment tray;

Task 6: The Extension grip: An oblong piece 6cm x 6cm and 0.5 cm thick is moved a distance of 3cm between pre-formed cut outs within the assessment tray.

4.4.3.3 *Activities of daily living (ADL) tasks*

Following the abstract object tasks, the activities of daily living tasks were undertaken. The tray was turned over to reveal the appropriate correct positions for each of the items used for each test, including starting and finishing positions. These positions are duplicated on each side of the tray, with the appropriate starting positions being used depending on the hand side (left or right) being assessed.

Figure 4.7: The daily living activities and the reversed assessment tray (author's own image).

Activity 1: Coins: Prior to this activity, a 1p and a 2p coin are placed at the edge of a small table. The 1p coin and 2p coin are picked up and placed in an empty jar, which is located within a predefined area on the assessment tray;

Activity 2: Button board: Four buttons sewn into a cloth on a card are undone in turn;

Activity 3: Cutting: A piece of 'plasticine' is cut into 2 pieces using the knife provided;

Activity 4: Page turning: A paper page is picked up from one side of the assessment tray, turned over, and put down on the contra- lateral side;

Activity 5: Jar lid: The empty jar lid is unscrewed and removed from the jar and placed on the assessment tray;

Activity 6: Jug pour: The jug is filled with 100ml of water prior to this activity.
The user empties the 100ml of water from the jug into the empty jar;

Activity 7: Carton pour: The juice carton is filled with 200ml of water prior to this activity.
The user empties the 200ml of water from the carton into the empty jar;

Activity 8: Full jar: The empty jar is filled with 200ml of water prior to this activity.
The jar is moved from one side of the assessment tray to the other, over the juice carton, which is placed on its side in the middle of the tray directly between the starting and finishing positions of the task. The carton effectively acts as a barrier; the subject must therefore lift the jar over the carton before replacing it on the appropriate position as marked on the other side of the assessment tray;

Activity 9: Empty tin: The empty tin is moved from one side of the assessment tray to the other, over the juice carton, which is placed on its side in the middle of the tray directly between the starting and finishing positions of the task. The carton effectively acts as a barrier; the subject must therefore lift the jar over the carton before replacing it on the appropriate position as marked on the other side of the assessment tray;

Activity 10: Tray: Prior to this activity, the assessment tray is placed at the edge of a small table and the open assessment case is placed in the middle of the table. The assessment tray is picked up by the subject and lifted from one side of the table to the other, over the open assessment case;

Activity 11: Key: The key within the lock in the inside of the case is rotated fully and released;

Activity 12: Zip: The zip within the inside of the case is opened fully and re-closed;

Activity 13: Screw: The screw device is turned through 90 degrees using the screwdriver provided;

Activity 12: Door handle: The door handle within the inside of the case is turned down fully and released.

An illustration of the SHAP assessment with a prosthesis user wearing the test prosthesis is shown in **figure 4.8:**

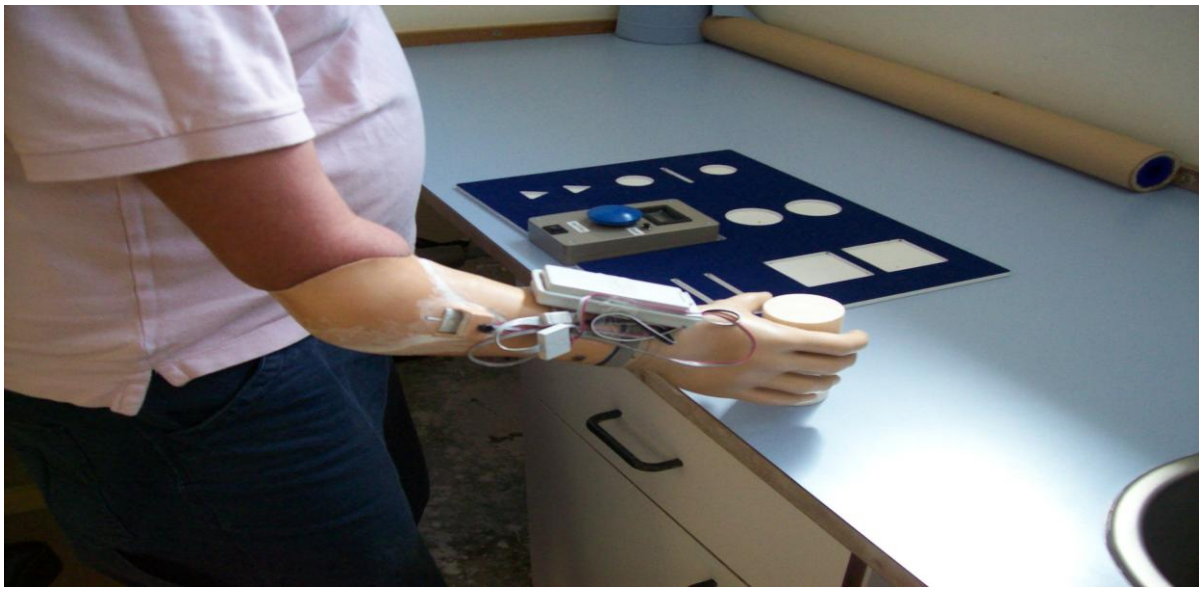


Figure 4.8 Prosthesis user 'B' with the test prosthesis and the SHAP assessment used in the pilot study

The electrode attachment test conditions were randomly switched between assessments to balance the effects of practise and improvement, and each assessment was carried out twice for each electrode arrangement. The electrode could be changed between being adhered using the plastic extensions, or placed within the standard housing with the plunger unscrewed (no pressure), or secured with the plunger screwed onto the electrode outer face, reasonably easily, although some increase to the standard housing aperture was necessary to allow the plastic extensions to fit against the skin without rubbing against the socket wall. Different electrodes, of exactly the same type, design and gain settings (model: Galateya NPF), were used by necessity in conjunction with test condition 2, since these need to have the semi-rigid rods removed to allow for the plastic tabs to be fitted (see **figure 4.3**).

4.5 *Results*

Each prosthesis user subject undertook the SHAP assessment 3 times, with each testing condition, over a period of two weeks. During each assessment, the conditions were swapped. For example, test condition 1 was tested first on the first visit, test condition 2 was tested first on the next visit and test condition 3 was tested first on the last visit by the subject.

Using the digital data entry tables supplied via the SHAP website at *http://www.shap.ecs.soton.ac.uk*, the functionality scores for each of the testing conditions were calculated and are shown in **table 4.2**. The mean scores are also displayed graphically below in **figure 4.9:**

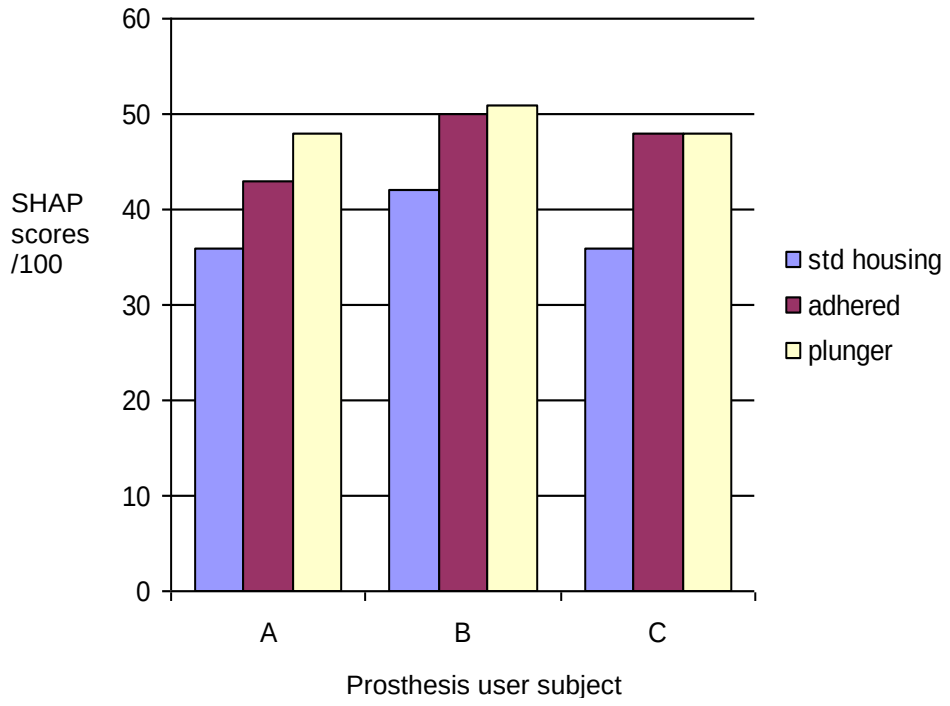


Figure 4.9: Average SHAP functionality assessment scores / 100, for each prosthesis user employing the three different testing methods described

Prosthesis user / Electrode arrangement	User A	User B	User C
	SHAP functionality assessment score / 100		
Test condition 1: Standard housing	*37*	*44*	*37*
	35	*45*	*33*
	36	*43*	*35*
Mean	**36**	**44**	**36**
Test condition 2: Adhered to skin	*47*	*50*	*42*
	44	*48*	*43*
	41	*50*	*40*
Mean	**44**	**49**	**42**
Test condition 3: Secured via plunger	*45*	*49*	*50*
	44	*50*	*42*
	47	*51*	*42*
Mean	**45**	**50**	**47**

Table 4.2: SHAP functionality assessment scores for each of the three testing conditions

4.6 *Statistical analysis*

A one-way ANOVA test revealed a **statistically significant difference** between the lower functionality scores acquired when employing testing condition 1 (standard housing) and the higher functionality scores acquired when employing testing condition 2 (adhered to skin) ($p=0.025$). There was therefore a statistically verifiable increase in the functionality available from the myoelectric prosthesis using electrodes adhered to the skin with respect to those housed in the standard fashion.

A one-way ANOVA test also revealed a **statistically significant difference** between the lower functionality scores acquired from testing condition 1 (standard housing) and the higher functionality scores acquired when employing testing condition 3 (secured via plunger) ($p=0.025$). There was therefore a statistically verifiable increase in the functionality

available from the myoelectric prosthesis using electrodes secured via the plunger with respect to those housed in the standard fashion.

A one-way ANOVA test revealed no statistically significant difference between the functionality scores acquired when employing testing condition 2 (adhered to skin) and the functionality scores acquired when employing testing condition 3 (secured via plunger) ($p=0.025$). There was therefore no statistically verifiable difference in the functionality available from the myoelectric prosthesis using electrodes adhered to the skin with respect to those secured via the plunger.

4.7 *Discussion*

The indexes of functionality scores attained in this study were significantly lower than those that would normally be attained by a natural human hand (89). These scores have been reported as being in the range of 95-100 for most subjects who have no significant problems with natural hand function (90). Metcalf et al (2008) also found similar levels of functionality scores for subjects with unimpaired hand function, stating an average score of 98 (91). However, this figure becomes significantly lower as subjects reach 65 years of age and beyond (91)

However, Kyberd et al (2011) also found in a study that identified gaze patterns and other factors involved in levels of myoelectric prosthesis functionality that the range of scores achieved by myoelectric prosthesis user subjects was significantly lower than those achieved with the natural hand (90). The SHAP functionality scores which Kyberd et al found did, however, vary considerably, ranging between 17 and 71 (90). The scores within the study outlined in this chapter did not appear to differ as significantly, with the lowest mean score being 35.8, for ‘user A’ employing the standard housing (test condition 1), and the highest mean score being 50.8, for ‘user B’ employing the housing unit with the plunger (test condition 3).

The results indicate that significantly greater levels of prosthesis functionality are afforded when the electrode is secured against the surface of the skin than would be achieved using a conventional standard socket/electrode housing arrangement. However, the method of securing the electrode to the skin was not statistically significant in terms of the results that

were achieved by prosthesis users who employed the electrodes that were secured via the external plunger.

This similarity in the available functionality afforded by both test conditions 2 and 3 is important to note. As noted in table 4.1, the SENIAM recommended best practice method for acquiring myoelectric signals is to attach the surface electrodes to the skin via adherent pads (170). Although this was eventually achieved within this study, it was by no means straightforward, and took a large amount of alterations to the socket and electrode in order for it to be accomplished. In addition, the electrodes were not attached to the prosthesis and therefore required reattaching in exactly the same, correct position each time the prosthesis was donned. For one-off myoelectric or ECG measurements, this method of securing the electrodes is suitable (170). For day to day usage, it may not be practical for prosthesis users. Employing adhered electrodes within a standard clinical arrangement may therefore not be a feasible answer to improving prosthesis functionality.

However, if an external method of securing the electrode is as functionally effective, as these results suggest, then using this as an alternative could produce important prosthesis functionality improvements on a par with those that would be achieved using standard best practice approaches (170). Furthermore, employing this method would be an easier option to fabricate and fit, and would still enable the prosthesis user to don and doff the prosthesis in the standard fashion, although it would mean that some adjustments to the electrode contacts may have to be undertaken each time the prosthesis is donned.

It should be noted that the differences in the overall index of functionality scores were due to large individual differences in specific times for certain individual tasks, and not due to generally lower times across the task and activity spectrum. In fact, for the majority of individual tasks, as outlined in section 4.4.3.1, there was little difference in terms of actual times taken for completion between all of the test conditions as trialled in this study. The larger functionality index values for the standard arrangement were mainly due to single, very large increases occurring during certain tasks undertaken using the standard housing method randomly for different tasks. These differences were possibly caused by loss of electrode contact during the task completion.

Certain tasks appeared to be more vulnerable to poor control and prehensor disruption. The task involving the picking up of coins and the turning of the door handle both showed a distinct jump in terms of the time taken during testing under condition 1, the standard housing. Subject 'A' reported difficulties during these tasks during condition 1, with slow response and loss of control. The same problem occurred with subjects 'A' and 'B' although not during the same tasks. The overall effect was to significantly lower the functionality index, even though only a minority of tasks and activities exhibited significantly different times during the testing regime.

The prosthesis user subjects in this study did comment on the loss of functional control at times and when particular tasks were being undertaken. Frustration with hand and prehensor control has also been noted in other studies and surveys within this field (44, 46). It is also considered to be a factor in prosthesis rejection. Reducing this frustration is clearly important if prosthesis usage and usability is to be improved (214).

4.8 *Limitations and potential errors*

Clearly, the small number of subject users available for this area of the investigation was regrettable. The number of users available for studies such as this is usually small, hence the large number of single-subject studies performed, as noted in **chapter 3**. In addition, using a different, albeit identical, electrode in one of the test conditions (test condition 2) naturally introduced a potential difference in equipment and therefore data output. However, the significance of the statistical differences, at a low 'p' value, again suggest that further study is required, and that the correlation between best practice signal acquisition and the use of an external local housing device is worth further consideration.

4.9 *Chapter summary*

The greater levels of functionality associated with the non-standard electrode arrangements generated from this study suggest that motion between the residual limb and the socket does affect the functionality of transradial myoelectric prostheses. The effect of locally maintaining the electrodes in a more secure contact arrangement with the skin surface can redress any potential loss of functionality caused by socket slippage over the residual limb. Using locally secured electrodes provided a level of functionality proportional to that achieved when the electrodes were completely separated from the prosthesis (except through the contact leads).

The introduction of position-adjustable, securely attached electrodes between the socket and the residuum may even allow myoelectric systems to be used within slightly loose sockets, e.g. for growing children, using the local contact pressures to maintain a secure vehicle for signal recognition. Further investigations are necessary to ensure that expensive prescriptions and technical alterations are not made to myoelectric prostheses when levels of functionality may actually be improved within the socket-electrode housing mechanisms at much less expense.

The results of this pilot study were limited by the small sample of prosthesis users employed, and the users' unfamiliarity with the equipment, both in terms of the prosthesis supplied and the functionality assessment methodology. However, the results do indicate that increasing the security of the contact between the residual limb and the skin during prosthesis usage can produce similar results to those acquired by securing the electrodes directly to the skin without interference from the socket or prosthesis movement.

Although the practice of adhering electrodes to the skin is commonly performed in non-prosthetic applications, this practice is impractical in terms of electrodes being donned and doffed within a prosthetic socket. It may be possible to supply similar levels of electrode security using bespoke electrode housing units and changes to the designs of conventional prosthetic socket arrangements. The effect of such designs on prosthesis functionality will be affected by the particular characteristics of each socket, and the Prosthetists' unique way of establishing the correct fit. Nevertheless, the results provided evidence which suggested that a longer term study, using larger numbers of upper limb myoelectric prosthesis users, was warranted to not only confirm the findings in a larger population, but also to enable further development of a housing unit suitable for mass production and commercialisation.

A further study was therefore performed which examined the efficacy of a new, interchangeable electrode housing device potentially improving interface contact and the subsequent acquisition of myoelectric signals in myoelectric upper limb prostheses.

Chapter 5:
The assessment of myoelectric prosthesis functionality using a bespoke electrode housing unit

5.1 *Introduction*

In the previous chapter, it was noted how electrode-skin contact variations could have a significant effect on the functionality scores for myoelectric prostheses. The use of an external plunger to facilitate adjustment of electrode to skin contact security was found to produce levels of prosthesis functionality on a par with adhering the electrode to the skin, which is currently viewed as best practice within the field of surface electrode signal acquisition (170).

Despite the obvious advantage (for donning and doffing the prosthesis) of using the plunger on the socket wall to secure the electrode to the skin, as opposed to using adherent tape, the plunger employed was still very crude and offered very limited adjustments other than basic improvement to electrode / skin contact. As well as this feature, there are other factors that may also influence the acquisition of the myoelectric signal which are inherently linked to the method of electrode contact within the prosthetic socket. This chapter explores these other factors and implements changes to the initial plunger design seen in **chapter 4,** with the result being a new bespoke electrode housing unit.

It was noted in **chapter 2** that the myoelectric signal travels along the length of the muscle fibre during depolarisation (160, 161). A differential electrode must therefore acquire the same myoelectric signal at all of the electrode contacts (reference, positive and negative) during the passage of the signal if this signal is to be effectively measured and employed as a control source (40). If it is not, then the respective signal strength differences between the contacts during the transition of the signal, which effectively determine its measurable value, will not be correctly acquired, and the signal strength will be compromised or lost (39, 40). At present, the standard electrode housing method used in myoelectric sockets does not allow any rotational shift or movement once it is positioned within the socket, and is completely reliant upon the skill of the Prosthetist to determine this correctly during the assessment and that this position is correctly and accurately maintained throughout the manufacturing procedure.

The positive and negative electrode contacts must also acquire the same myoelectric signal strength as it travels along the fibre; this may not only be altered by electrode alignment with respect to the skin, but also by the pressure variance between the positive and negative differential contacts with respect to the skin (201). The amount of tissue between the muscle and the skin will affect the signal strength received-if the pressure between each contact and the skin varies this will, in theory at least, lead to differences in tissue displacement and therefore potentially different thicknesses of tissue that will absorb and affect the signal transition between the muscle and the skin (158, 159, 163, 164, 166). As shown in **chapter 2**, tissue consistency and thickness has been reported in numerous studies as a factor in signal acquisition; the link between subcutaneous fat and signal acquisition was most significantly highlighted by Kuiken et al (2003), who used finite element analysis of the depth of fat vs. signal reduction, and stated that the existence of fat layers 'may pose considerable problems in the control of myoelectric prostheses' (164).

The aim of the investigation reported in this chapter was to develop and test a new electrode housing design which could offer more finite adjustment of electrode position within the housing unit by allowing positional change around the longitudinal electrode axis, but also finite adjustment at each longitudinal contact. In addition, the electrode housing unit needed to be self-contained, to allow adjustment and re-positioning (if appropriate) over the optimal signal site.

The following sections give an initial background of the types of electrode and housing designs currently available and how these designs informed the development of a novel electrode housing unit to feasibly improve myoelectric prosthesis functionality.

5.2 *Current methods for socket-housed electrode designs*

A number of socket-housed electrode designs have historically been used to achieve the goal of detecting and transmitting myoelectric signals (4). Earlier types, such as the RSL Steeper SEA200C (**figure 5.1**), relied on a rigid housing that enabled the electrode to be 'snap-fitted' intimately into place within a definitively-shaped housing created from plastic 'dummy electrodes' placed on the plaster cast prior to socket lamination (see **figure 5.1**). These types of housings allowed for the addition of plastic spacers that could be placed between the housing and the electrode face if a firmer contact with the skin of the residual limb was required.

Figure 5.1: RSL Steeper SEA200C (247)

Figure 5.2: RSL Steeper SEA200 (248)

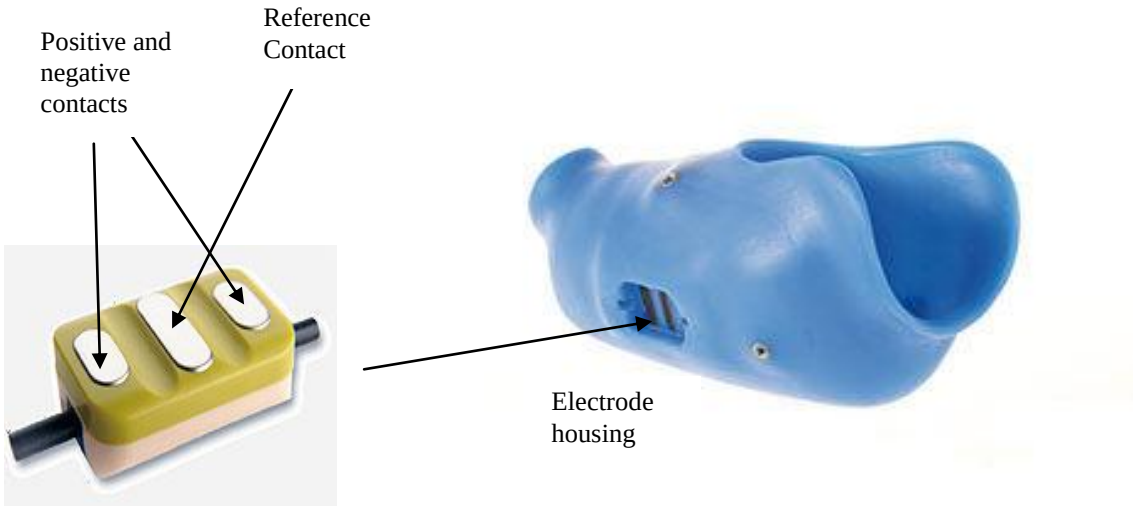


Figure 5.3*:* The standard housing of the electrode within the socket walls, via semi-rigid locators. The electrode on the left is the latest i-limb electrode (SPS 800.767.7776), but still uses a similar arrangement as others such as the SEA200 (249). The socket on the right is the latest Otto Bock myoelectric silicon insert-fitted socket, the SiCOX, which again still incorporates a standard housing section, which accommodates the electrode in a fixed position (250).

More recent designs for electrode housings, such as the SEA200 (**figure 5.2**), rely on the use of semi-rigid locators, which extend from each end of the electrode and attach into

pre-prepared structures, again created from dummy spacers which are used during lamination over the original cast (251). The semi-rigid locators are fitted within a dummy housing specifically manufactured to accommodate the electrode shape and the locaters (see **figure 5.3).** All three of the electrodes named in **figures 5.1, 5.2. & 5.3** are differential electrodes, of the type described in **chapter 2**. Each type therefore has three electrode contacts to acquire and amplify the myoelectric signal and remove the common mode voltage; the positive and negative contacts are annotated, and are clearly located on either side of a reference contact (see **chapter 2**). All three must be in close contact, with equal pressure distributed across the length of the electrode, if optimal signal acquisition is to be achieved.

The original electrode position within the fixed housing is very much dependant on the skill of the Prosthetist and neither of these housings allow for any adjustment once they have been secured within the socket walls (251).

As discussed in **chapters 1 and 2**, the method of housing the electrode within the prosthetic socket has not altered substantially during the last few decades, in contrast to the development of more sophisticated control mechanisms and prehensors during this time. There was therefore a need to undertake a pilot study investigating the effects of different arrangements of electrode mounting within the prosthetic socket on prehensor functionality, in order to realise the potential of newer terminal devices. In particular, the lack of available options to improve electrode contact to the skin during prosthesis usage encouraged the development of an innovative method to provide easily-adjustable electrode-skin contact intimacy with the skin of the residuum by designing a novel electrode housing unit.

5.3 *Clinical myoelectric assessment*

To achieve the correct electrode positioning within the socket that provides maximum signal strength, a standard clinical assessment process for electrode positioning is undertaken (4, 72). The maximum available signal strength that the potential prosthesis user can achieve from each muscle group should be measured and noted. This is normally undertaken via the use of either a clinical myoelectric assessment system, which measures and records the myoelectric signal strength and pattern, or can sometimes be found by simply employing the use of a myoelectric hand or prehensor (4, 72). The latter is less suitable, as the actual signal strength is not deduced, merely whether the user can affect control. As such, the maximum signal strength may not actually be selected, since most systems would be threshold

controlled (see **chapter 2**) and unaffected by increases in signal strength beyond the minimum threshold level required for hand or prehensor activation (39).

It is important that the each relevant muscle group within the residual limb of the potential prosthesis user is assessed, and whether it can achieve at least the minimum threshold signal strength (see also **chapter 2**) that is required to initiate myoelectric operation (31). Although the minimum signal strength required for hand or prehensor activation is normally 15 micro-volts, in reality the Prosthetist will try to find a site on the muscle that can produce around 30-40 micro-volts, because this will take into account factors such as muscle fatigue during usage, which will reduce the signal strength over time (39, 72).

The myoelectric assessment procedure is outlined in **Appendix C**-*Clinical and technical methodologies.* The appropriate muscle bulk is selected; for transradial prostheses, this will be the remains of the wrist flexors and wrist extensors (see **chapter 2, tables 2.1 & 2.2**). The extensors are normally used to open the prosthetic hand or prehensor in transradial prostheses, with the flexors used to close the hand or prehensor (39). The electrode will be placed on to the skin, in what is perceived by the Prosthetist as the natural alignment of the muscle fibres. The prosthesis user will then be asked to contract the target muscle that is being assessed, and the signal strength is recorded, or the hand function noted. The electrode is moved in sequence around the muscle belly, to find the optimal signal site. The lateral edges of the muscle are generally avoided, as these may lessen the signal clarity (171, 186). However, identification of single muscles within the muscle groups is challenging since, as was noted in **table 2.1**, **chapter 2**, there are many numerous muscles within the forearm. The more experienced the Prosthetist, the more likely that a correct electrode location is noted.

Once the correct location has been identified, it is marked with an indelible crayon and the negative cast is taken over this impression. This will then be transferred onto the three-dimensional positive cast, which will be used by the technicians to identify the correct location prior to socket manufacture.

5.4 *Manufacturing the electrode housing*

Standard manufacturing procedures for sockets are outlined in **Appendix C**-*clinical and technical methodologies*. As previously stated within **chapter 2**, standard myoelectric prosthetic sockets are manufactured with specialised ‘dummy electrode housings’ within the

socket walls during the initial laminating process (249). These housings are positioned over the flattened areas of the cast that the Prosthetist had selected as the optimum electrode contact sites. Standard practice employs the use of two electrodes (located respectively over the remains of the flexor and extensor muscles, see **chapter 2**), and therefore two dummy housings are normally employed (one for each electrode) (39, 40, 72, 73). The dummy housings create an attachment position within the socket for the electrode, with the electrode contact positions over the residual limb being determined by the shape of the cast where the dummy housing is situated (**figure 5.3**).

The 'dummy housings' are normally secured to the cast via the use of screw fastenings that attach the central portion of the dummy housing to the cast in the correct location (249). Alternatively, adherent tape may be used, if the cast is considered to be too fragile for the attachment of screws (249). In either case, it is vital that the dummy housing stays securely fastened in exactly the same position and alignment and previously determined during the assessment. Movement may occur, particularly if the use of tape is employed, when the layers of stockinet are applied during the lamination process (see **chapter 2**). The stockinet must be tightly fitted over the cast, meaning that the housings may move is the method of securing them is compromised. Even the use of a screw fastening may allow the electrode dummy to rotate away from its optimally aligned position. Similarly to the assessment process, the manufacture of the socket relies upon the skill and experience of the technician undertaking the process.

5.5 *The effect of alignment and other electrode positional variations*

Achieving a secure and intimate fit between the electrode and the residual limb within the socket of a myoelectric prosthesis is generally regarded as essential for uninterrupted prosthesis usage and control (184, 194). The results from the pilot study in **chapter 4** also suggested that fixed electrode housings do not always deliver optimum contact. However, the security of this interface is not the only factor requiring consideration with regard to signal acquisition. The myoelectric signal will pass along the length of the muscle fibres and, for the electrode to acquire it evenly across all of the contacts, the electrode will in theory have to be positioned parallel to the muscle fibres when the electrode is housed within the prosthetic socket (31, 39, 40, 169).

Anecdotal evidence suggest that common clinical practice is to follow the natural alignment of the residual limb and place the electrodes parallel to this alignment above the site of maximum signal strength. However, the remains of the muscle tissue, and how it presents upon palpation of the residual limb, may differ between prosthesis users, particularly at the transradial level of limb absence which has multiple wrist flexors and extensors (see **tables 2.1 & 2.2, chapter 2**). Factors such as cause of limb absence, nature of the injury (if the cause was traumatic) plus any unique techniques employed during surgery will all contribute to differences in the layout of the muscle tissue and importantly its alignment with respect to the residual limb.

Palpation of the residual limb may offer some information with regard to the optimum alignment position of the electrode. However, the presence of other soft tissues may make precise muscle location more difficult. In addition, within the transradial residual limb there are a number of different muscles which contribute to the overall muscle mass, and these muscles may cross over each other, making an initial electrode position selection more difficult (see **tables 2.1 & 2.2, chapter 2**).

The transmission of the myoelectric signal is also dependent on the alignment of the muscle fibres with respect to the electrode contacts (40). Each of the 3 contacts must be aligned along the long axis of the same muscle fibres in order for the same signal to be acquired by each contact. If not, then the contacts will potentially acquire different signals from various muscle fibres, causing disruption to the clarity of the signal and potentially failing to initialise a response from the prehensor (39, 40, 157-160, 174, 175).

In addition, keeping the electrode along the long axis of the bulk of the muscle fibres will maximise the signal strength, since the signal acquired will be the summative voltage of all the fibres that are in acquired via the surface electrode (169). Misaligning the electrodes will also increase the chance of cross-talk, where muscle fibres from muscles other than the target muscle may affect the signal acquisition of the electrode and hence the operation of the prehensor (39, 40, 157-160, 174, 175).

The problem for the Prosthetist is that the alignment of the muscle fibres is not necessarily clearly defined on the surface of the residual limb. Remnants of multiple muscles may contribute to the myoelectric signal that is acquired from the surface of the skin at the

transradial level. Re-attachment of these muscles following amputation may result in the fibres becoming aligned in a non-specific pattern, meaning that there may be no discernible 'norm' with regard to electrode alignment (95, 96, 100).

For prosthesis users who have a congenital limb absence, the muscle structure within the residual limb will often vary due to the unique genetic causes and subsequent characteristics of the limb malformation (99). For these reasons, it is difficult for the Prosthetist to be sure that the electrode is actually aligned in an optimum position with regard to signal acquisition, even if they have experience of fitting myoelectric prostheses. For those Prosthetists who have limited myoelectric prosthesis fitting experience, the task is even more challenging.

Surface electrodes have a large myoelectric signal pick-up area (171, 210). Essentially, the cumulative effect of many fibres both close to the electrode and relatively far from it will be recorded (171, 210). This is both advantageous and disadvantageous; many fibres will produce a larger cumulative effect and hence a stronger signal, but the disparate sources will potentially provide fluctuating signal strengths and cross-talk, which will interfere with the signal acquisition process (39, 40, 157-160, 174, 175).

Each muscle fibre will contribute to the overall myoelectric signal at the skin's surface by a value equivalent to $1/r^n$, where 'r' is the distance between the electrode and the muscle fibre and 'n' is an arbitrary constant disputed in value by various authors (158, 201). Therefore, a larger electrode-to-fibre distance will provide a lower contribution to the summative myoelectric signal, thereby highlighting the need for the electrode to be placed over the largest number of target fibres to acquire the maximum summative signal.

Muscle force during isometric contraction is often regarded as being proportional to the resultant myoelectric signal strength, but variations have been reported (158, 165, 183, 250, 251). This may be due to the changes in recruitment of slow twitch and fast twitch fibres, which may alter the signal size as contraction progresses (39, 250). This could potentially result in prosthesis users attempting to apply greater levels of contractile force but not producing proportionally larger myoelectric signal sizes and thereby not receiving appropriate prosthesis feedback from their actions.

Although research on the subject area is limited, there is some evidence to suggest that electrode alignment plays a significant role in the variations in acquired signal strength, although whether this role is as significant as electrode pressure or contact is disputed (166, 167, 201). Current electrode housings within the prosthetic socket also secure the electrode in a fixed alignment position (249). Therefore, if the electrode is significantly misaligned, the prosthesis may require a completely new socket, and sometimes even a new limb entirely, due to the exoskeletal construction used in most upper limb prostheses (1, 4, 23). In addition, the prosthesis user may not realise that misalignment is the reason for problematic prosthesis usage and may actually mistakenly abandon myoelectric limb wearing believing that there is simply not enough signal available or that there is a fault with the prosthetic system or componentry. Myoelectric prosthesis rejection is commonly cited, with functional problems often quoted as a reason for lack of usage (6).

However, it should be remembered that the effect of misalignment, especially when minimal, is not clearly understood in terms of its effect on resultant prosthesis functionality. In addition, any apparent variations in the amount of electrode alignment between Prosthetists for a given prosthesis user are again not well documented. Any new design of electrode housing device would therefore need to offer the capability of applying viable variations in electrode alignment and should be able to afford prostheses usage and data collation from these different positions.

An intimate prosthetic socket fit is designed to limit movement between the residual limb and the prosthesis for a number of reasons; as discussed in **chapter 2**. However, variances between what could be perceived as a ‘good fit’ by both the Prosthetist and patient are also relayed frequently, if anecdotally. Factors such as tissue stiffness, shape and volume match, cause of limb absence and the user’s own personal preferences will all contribute to small but nonetheless significant changes to the socket fit (4, 42, 102, 128, 139). These become particularly significant when considering the nature of myoelectric control and the importance of the electrode-skin interface.

There can be little doubt that movements, even minute ones, can occur between the skin covering soft tissues and a solid interface such as the prosthetic socket (42). It is, however, less clear as to what extent these movements occur during ADLs and more specifically what impact these have on differential electrode contact security and signal

acquisition as well as prosthetic functionality. Variances between the perceived tightness of myoelectric sockets and electrode contacts and their relationship with prosthesis response and control were highlighted in **chapter 3.** In addition**, chapter 4** provided a comparative assessment between various basic electrode-to- skin attachment methods and their association with resultant prosthesis functionality. However, the ability to enhance electrode to skin contact using finite alterations within a feasible system that can be implemented within a commercial myoelectric prosthesis is still unavailable at present.

Maintaining contact between the skin and the residual limb during prosthesis operation is widely reported as being essential in achieving effective signal acquisition (39, 40, 160). The production of motion artifacts however is not the only problem caused by poor contact. Lack of prehensor activation (as described in **chapter 3**), and relative motion between the electrode and the muscle belly away from its original position, both reduce the capability of the prehensor and potentially the functionality of the prosthesis. Not only would the signal from the target muscle group be reduced if the electrode position moved with respect to the residual limb, other factors such as cross-talk could further diminish the clarity of the signal (39, 40, 157-160, 174, 175).

According to anecdotal evidence, current practice employed to improve the security of electrodes such as the SEA200 (**figures 5.2 & 5.3**) involves the application of elastic bands wrapped around the outside of the electrode surface and outer socket wall. The tension within the elastic should impart reasonable force onto the electrode to help to maintain immovable contact. However, the flexibility within both the elastic and the semi-rigid electrode locators will by necessity allow some degree of motion to occur. In addition, the tension created within the socket will be related to the tightness of the socket tightness. However, in **chapter 3** it was noted that socket tightness did not have the same effect on prehensor or hand control as electrode tightness. Therefore, it should not be assumed that the provision of a tight socket without direct electrode contact improvement is sufficient to improve prehensor control; and as a result, prosthesis functionality.

The fit of the socket and the electrodes to the residual limb requires a great deal of skill if suitable secure electrode-to-skin contact is to be achieved (222). Even then, as the muscles contract inside the socket, there is a tendency for the shape of the residuum to alter

within a fixed environment, thereby potentially altering the contact scenario between the electrode and the skin (4).

The results of the pilot study described in **chapter 4** showed that the use of a simple attachment unit incorporated into the design of the prosthetic socket enhanced myoelectric signal acquisition and produce improved functionality when compared to the standard electrode housing arrangement. However, there were obvious limitations to both the electrode housing arrangement used and also to the prosthetic socket, which were as follows:

1) The housing was fixed within the socket walls and, as per the standard housing arrangement, in a position that relied upon the skill and experience of the Prosthetist.
2) There was no means to change the alignment of the electrode with respect to the underlying muscle fibres of the residual limb.
3) The single plunger in the centre of the housing unit did not impart contact security onto the most important areas of the electrode (i.e. the contacts positioned at either end of the electrode), and did not provide the means to maintain similar security for both contact areas.
4) All three prostheses were constructed to suit the requirements of the three users employed within the pilot study. Although every effort was made to ensure consistency in the design and manufacturing of each prosthesis, minor differences in length and materials employed may have led to a slight lack of consistency between the results obtained from each user.

It was therefore thought prudent to design a further study which took account of the limitations highlighted in the pilot study reported in **chapter 4**.

5.6 *Proposed changes to the Socket housing*

A new socket housing device was designed to improve and facilitate:

1) The ability to alter the position of the socket housing;
2) Development of the design of the plunger apparatus, and
3) The ability to alter alignment of the electrode within the housing device, both in rotational orientation and position in relation to the skin surface.

5.6.1 *The general movement flexibility of the socket housing*

Current electrode attachment methods within standard myoelectric sockets are fixed within a position determined by the Prosthetist. As a result, the clarity and strength of the signal acquisition is still very much determined by the ability of the Prosthetist to locate an effective electrode position and indeed for this position to be accurately transferred to the socket during the manufacturing process. Ideally, given the facts described in previous chapters about variations in signal strength and the production and dissipation of the myoelectric signal, the new electrode housing design should provide for some adjustment with respect to its position and contact over the residual limb even after completion of the manufacturing process. Indeed, this principle is keenly observed in almost other aspects of prosthetic treatment and provision. For example, the Prosthetist is not expected to initially provide the finalised set up, alignment and position of componentry in lower limb prostheses. Lower limb prostheses include numerous modular components offering multiple adjustment features to allow numerous post-fitting adjustments for the Prosthetist to assist the prosthesis user. For optimum performance, the electrode housing to be employed for this study would therefore need to be adjustable and indeed movable in terms of its positioning over the residual limb. This would be achieved by making the housing unit an external attachment to the socket – rather than being laminated into the socket itself.

5.6.2 *The plunger apparatus*

The single plunger used in the provisional electrode-skin contact assessment (see **chapter 4**) allowed contact adjustment to be applied to the central compartment of the electrode. However, this corresponded to the contact area that was covered by the reference, or central, contact of the electrode (see **figure 5.3**), and not the two differential contacts at each end of the electrode, which were more likely to provide motion artefact signals should contact be lost between their surfaces and the skin of the residual limb. In addition, the degree of contact security needed to be ideally maintained equally at both of these contacts; something which is difficult to achieve with just a simple, centralised plunger. Consequently, a dual-plunger arrangement was included within the new electrode housing device, with two plungers located in positions corresponding to each differential contact at each end of the electrode, enabling contact security to be individually adjusted at each location (**figure 5.8**).

5.6.3 *The design and manufacturing process for the novel housing device*

The electrode housing unit would need to be dimensionally-appropriate to remain proportionally sized for use in transradial sockets and to allow normal functioning of the myoelectric prosthesis. Excessive size and / or weight of the housing unit could potentially compromise the usability of the prosthesis. However, it would need to securely house a standard electrode with the appropriate dimensions, and in addition would also require enough space to enable the electrode to be moved into different alignment positions, in accordance with the requirements as outlined in section 5.3.3.

The housing unit would also have to be strong enough to incorporate a plunger system, similar in design to that employed in the pilot study, but this time incorporating 2 plungers, appropriately positioned over each end of the outer surface of the electrode in line with each of the electrode contacts once the electrode was secured into the unit. However, the differing contours of each transradial socket would require the housing unit to be flexible, or at least to consist of a material that could be moulded into the correct positions and socket surface contour without damaging the unit or its ability to house the electrode. In addition, the unit would require the means to be fastened to each socket without distorting the fit or compromising the comfort of the socket, and be able to be positioned as defined by the Prosthetist.

To meet these requirements, an initial drawing of the electrode housing device was produced, in accordance with dimensions measured from the standard electrodes that would be used in the study. From these drawings a template made from stiff card was created, and the electrode was fitted into this to check that the dimensions were accurate and that the proposed positions for the plungers were correct. For ease of construction and to allow for the analysis of a finite number of distinct electrode alignment positions within each socket aperture, the initial design of the housing unit only allowed a finite range of rotational positions into which the electrode could positioned within the housing. These positions, which would define the maximum rotational positions of the electrodes away from the assessed alignment identified by an experienced Prosthetist, were identified by evaluating the maximum rotational electrode positions with respect to this assessed alignment as determined by student Prosthetists.

5.6.4 *Identification of maximum electrode rotational alignment*

With regards to rotational position of the electrode within the housing, it was necessary to initially define the maximum rotational variations which less experienced Prosthetists may recommend following patient assessment in a clinical setting. To this end, a group of undergraduate prosthetic students were recruited who had received initial training in providing prosthetic myoelectric sockets. They were asked to produce casts of the residuum of a group of volunteer transradial amputees who were experienced in upper limb myoelectric prosthesis use. From the data received, it was possible to determine the maximal rotation variations in electrode alignment which these inexperienced clinicians would prescribe.

Six transradial prosthesis users with experience of using myoelectric control were recruited for this study. Volunteer subjects were required to be experienced in using a myoelectric prosthesis, be aged over 18 with transradial limb absence from any relevant cause, and have acceptable cognitive ability to be included in the study. Each patient was assessed and cast by an experienced Prosthetist and also by each of the students.

Following this assessment of the perceived optimal electrode position its rotational orientation by both the students and the experienced Prosthetist, a total of 26 positive plaster casts were eventually deemed suitable for inclusion in the study. The electrode positions determined by the student Prosthetists were measured against those identified by an experienced Prosthetist by using anatomical landmarks. The landmarks utilised as reference points were the epicondyles of the humerus and the centre point of the distal amputated end of the ulna (**figures 5.4 & 5.5**). The angle between the line representing the superior edge of the electrode housing and the line joining the medial or lateral epicondyle of the humerus to the centre point of the distal amputation site of the ulna were deemed to be the rotational angle of the electrode housing. The angles were measured using a hand-held goniometer. **Table 5.1** demonstrates the angular data for both medial and lateral housing unit alignment for each of the casts compared to the perceived alignment assessed by the experienced Prosthetist**.** The alignment configuration was classified as ‘nose up’ or ‘nose down’ referring to the pitch of the electrode facing the distal aspect of the cast (see also **figure 5.8).** Whilst large variations existed, the maximum angular displacement from the assessed electrode position was interestingly 25 degrees both in the ‘nose up’ and ‘nose down’ directions.

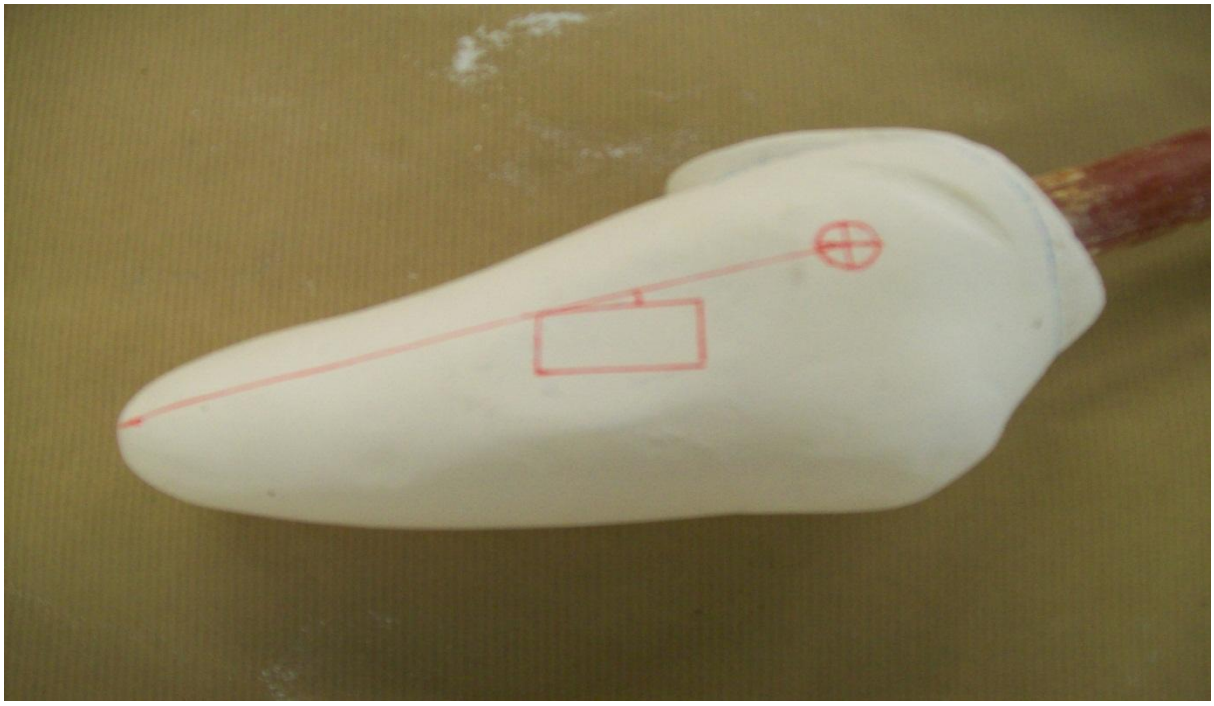


Figure 5.4: Cast of subject 'D' showing position of electrode in standard position as determined by experienced Prosthetist and current best practice.

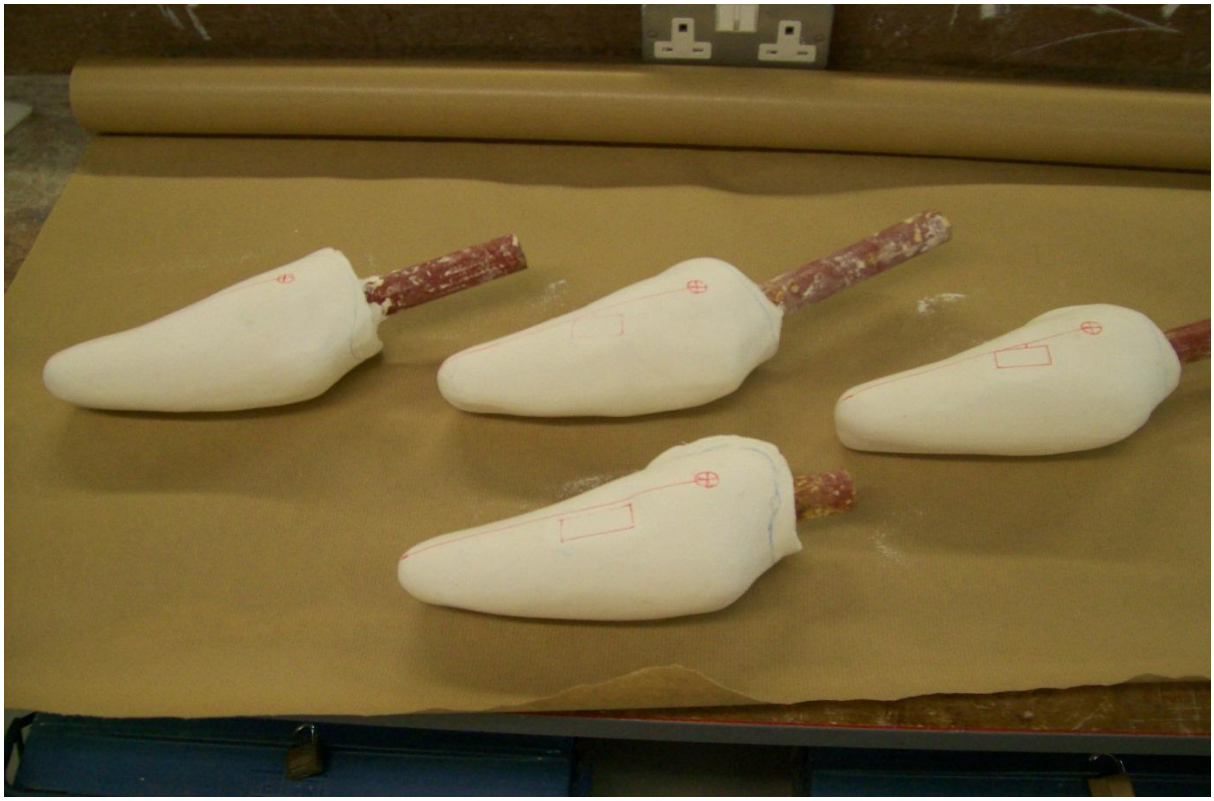


Figure 5.5: Casts being assessed for alignment variations with regard to 'the experienced' standard.

Student no.	Patient /subject	Medial electrode		Lateral electrode	
		'Nose up' shift/ °	**'Nose down' shift/ °**	**'Nose up' shift/ °**	**'Nose down' shift/ °**
1	(A)	-	4	10	-
2		10	-	8electrode	-
3		2	-	-	-
4		-	20	-	15
5	(B)	15	-	15	-
6		10	-	10	-
7		-	-	15	-
8		5	-	5	-
9	(C)	10	-	5	-
10		8	-	5	-
11		-	12	10	-
12		-	15	5	-
13		10	-	5	-
14	(D)	17	-	5	-
15		20	-	10	-
16		25	-	15	-
17		12	-	10	-
18	(E)	10	-	5	-
19		8	-	5	-
20		12	-	-	20
21		-	20	-	15
22	(F)	-	20	-	25
23		-	25	-	25
24		-	-	-	15
25		12	-	-	-
26		15	-	-	20

Angular shift = anterior aspect of electrode rotated 'nose up'

Angular shift = anterior aspect of electrode rotated 'nose down'

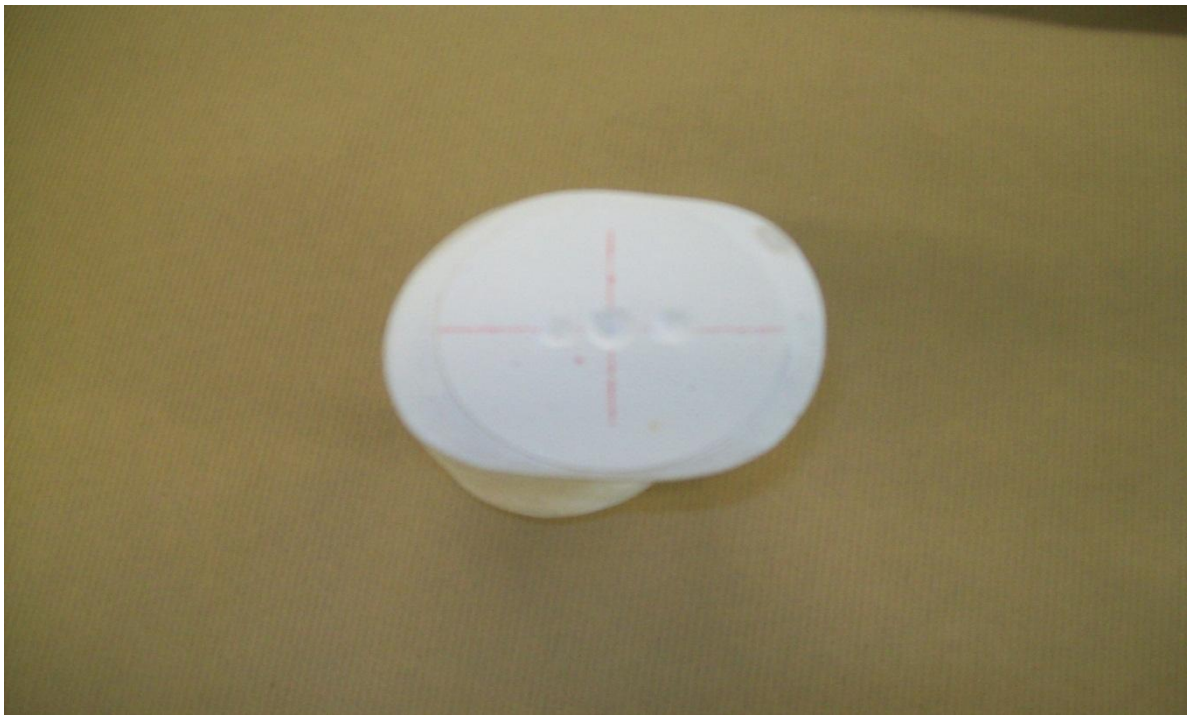
Table 5.1: Electrode rotational alignment variations compared to reference alignment**.**

The maximum rotational variations of the electrodes from the assessed alignment were then considered to represent the limit of changes that may realistically occur when less experienced Prosthetists undertook myoelectric assessment for electrode positioning within the socket and housing. Securing the electrodes into each of these positions and then completing a functionality assessment for the bespoke prosthesis for each separate location could then determine if noticeable functionality variations were evident.

5.7 *Design, development and proof of concept of the novel bespoke electrode housing unit.*

Laminated thermosetting plastic (Otto bock 'orthocryl' resin 617H17) was chosen as the material to be used in the manufacture of the housing. The laminating procedure is outlined in **Appendix C-** *clinical and technical methodologies*. Although this is not as pliable as thermoplastic, it could be heated and remoulded relatively easily, and could be manufactured within a standard prosthetic workshop environment. The resin used was mixed in an 80:20 proportional mix between rigid and flexible resins, which allowed sufficient strength for the socket to enable it to mimic a standard socket with an exoskeletal outer, but which was also flexible enough to be heated and moulded if required. The tensile strength of the housing unit was increased by the inclusion of nylon stockinet, which was thicker around the areas of the unit that would support the upper frame, which housed each of the two plungers, in a manner similar to that used in the pilot study.

The initial shape of the housing unit, and more importantly its contour with respect to the sockets onto which it would be attached, needed to be a close match to each socket for cosmetic reasons. To facilitate this, a cast from each of the volunteer myoelectric prosthesis users was obtained, and a plaster model was produced to form a suitable contour (see **figures 5.7 and 5.8**). The dimensions from the original card template previously taken were carefully and accurately transferred onto this cast, including the important areas that the electrode would require to be positioned securely in each of the three alignment positions previously determined (**figure 5.6)**. The housing unit was larger than the original standard housing fitting, since the three alignment positions (i.e. the original optimal position, and two further positions; each rotated 25 degrees on either side of this datum position) would naturally require a larger central area to allow for the electrode to be secured within each one. The relative aperture in each socket would also be larger than for the standard socket housing, for the electrode to fit securely against the skin in each position.



Figures 5.6 (side view) and 5.7 (superior view): Plaster cast used to create the electrode housing units.

The housing unit was also constructed from laminated resin, which was pliable enough upon heating for it to be moulded and remoulded onto the slightly varying socket contours that exited within the sockets that were included within the study.

Once the housing units were laminated, small threaded plungers were fitted into screw-threads created in the appropriate positions. The grooves which would house the flexible socket locaters were carved into the plastic, and the ends of each of the units were thinned to allow this to be more flexible and to sit more closely to the socket face, thereby enabling the electrode to fit closely to the skin of the residual limb.

The electrode housing units were themselves secured to the socket via small screws, fastened at each end of the housing unit (**figure 5.8**). The laminated material could be softened and adapted to each socket shape to allow for variances in contour and size, yet still provide an intimate fit for the electrode against the surface of the skin. Each housing unit had 3 separate positions: firstly, **bespoke 1**, an assessed electrode position as determined by an experienced Prosthetist; **bespoke 2**, the maximum electrode alignment (25°**) 'nose down'** with respect to bespoke 1**,** determined by analysis of student Prosthetist electrode locations; **bespoke 3**, the maximum electrode alignment (25°**) 'nose up'**, with respect to bespoke 1, also determined by analysis of student Prosthetist electrode locations.

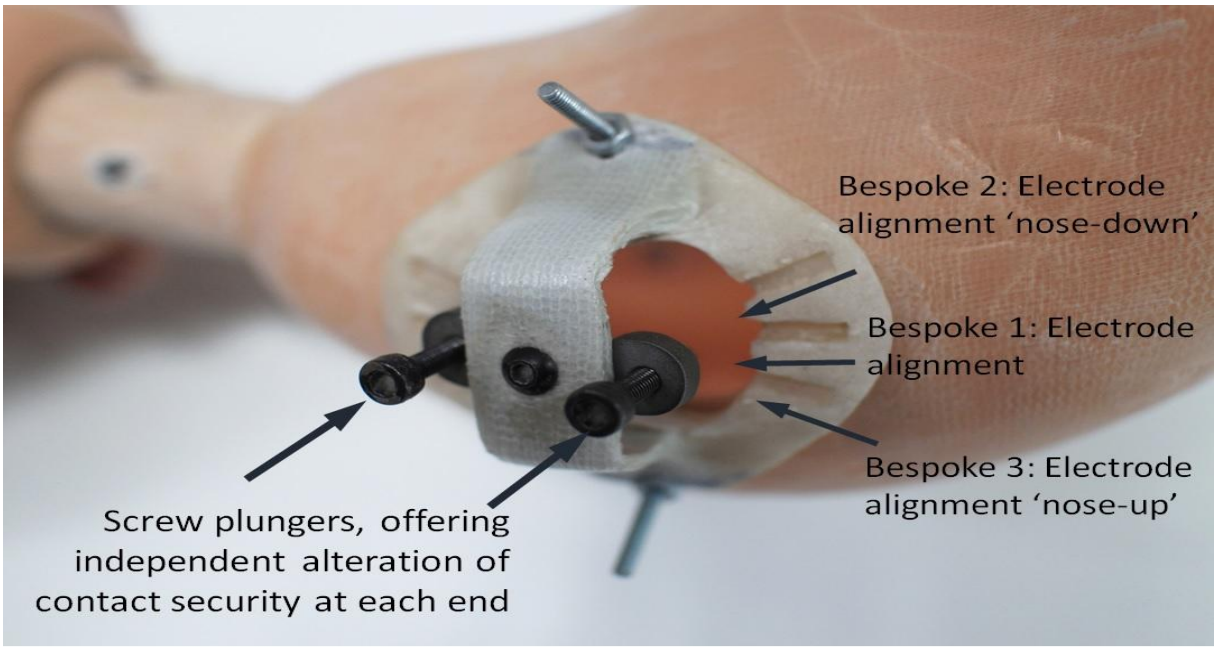


Figure 5.8: An illustration of the electrode housing unit attached to the socket for subject 'C' and the 3 electrode alignment positions available.

The electrode housing unit also incorporated 2 screw plungers, which could be used to intimately position each electrode contact onto the surface of the skin. This arrangement contrasted with the standard attachment of the electrode contacts within myoelectric sockets, which cannot be independently altered with respect to the surface of the skin. The screw

plungers enabled the Prosthetist to create the most intimate yet comfortable fit for the prosthesis user (the users themselves were able to adjust the unit to ensure that the electrode contact was at their perceived most effective and comfortable setting).

The bespoke electrode housing unit was used in conjunction with standard sockets, which also were able to house the standard electrode housings. Both methods of electrode housing were used in conjunction with the SHAP functionality assessment to test the available functionality that was available from each test condition. A total of 4 available conditions of electrode alignment and housing were therefore assessed, 3 within the bespoke housing unit, and 1 from the standard housing condition.

5.8 *Methodology*

The following methodology describes an investigation into the effect of electrode alignment and contact security and its effect on myoelectric prosthesis functionality. The hypothesis of this study was that alteration to prosthetic socket design to develop new electrode application techniques would improve the functionality of current myoelectric prosthetic devices worn by individuals with partial upper limb absence.

This study therefore examined electrode alignment position and perceived electrode contact security within the prosthetic sockets of a group of six prosthesis users and their subsequent effect on myoelectric prosthesis functionality when utilising a novel bespoke electrode housing device. A validated, reliable functionality assessment procedure, the Southampton Hand Assessment Procedure (SHAP) was employed to provide functionality assessment scores using both standard prosthetic sockets and those with the electrode housing device (89). All the prosthesis users were proficient users of myoelectric prehensors, and presented with various causes of limb absence.

5.8.1 *Investigation processes*

Prior to the commencement of the study, ethical approval was received from the appropriate United Kingdom NHS COREC ethical committee (see **Appendix B-***Ethical approval and related documents*). For each user, a fully functional transradial myoelectric socket with prosthesis attachment was manufactured. Six volunteer prosthesis users, who had previous recent experience using a transradial myoelectric prosthesis, were recruited for this study, from prosthetic service centres within the North West of England, UK. The selection

procedure is outlined in section 4.4, **chapter 4**. Relevant ethical approval documents, together with a patient consent form, can be viewed in **Appendix B**-*Ethical approval and related documents.* Associated documents with this investigation also included a patient information sheet, patient consent form and an investigation protocol adapted from those available within **Appendix A**-*Questionnaires and Questionnaire development* with alterations provided detailing the differences in the analysis regime associated with this particular investigation.

Volunteer subjects were required to be appropriately experienced in using a myoelectric prosthesis, be aged over 18 with transradial limb absence from any relevant cause, and have acceptable cognitive ability to be included in the study. All volunteer subjects signed a consent form (**Appendix B** - *Ethical approval and related documents*) after reading a patient information sheet (**Appendix A**-*Questionnaires and Questionnaire development*).

The prosthesis attachment was identical for each socket. Standard practice is to fit the myoelectric prehensor as part of an exoskeletal prosthesis. However, for the reasons of experimental standardisation and consistency, a bespoke endoskeletal prosthesis was created (see **figure 5.9**). This bespoke prosthesis consisted of a standard laminated myoelectric socket with a plastic tubular unit housed within the distal end. A separate wrist unit, originally designed and devised by the author, was also manufactured. This wrist unit was screw-fastening, and was manufactured with the relevant dimensions that allowed it to be securely fastened onto a standard RSL Steeper ‘Select’ myoelectric hand, MYA445. At the wrist unit’s proximal end was another plastic tubular unit, identical to that laminated into the distal end of the myoelectric socket. Connecting these two prosthesis components was a robust section of aluminium tubing, which could be adjusted and screw-fastened into both plastic tubular units. The aluminium tubing could be adjusted to suit the specific length requirements of the prosthesis user. Each myoelectric socket, for each separate prosthesis user, could be interchanged with the same components. As a result, the outcomes would not be altered potentially by the use of separate forearms or other components between prosthesis users.

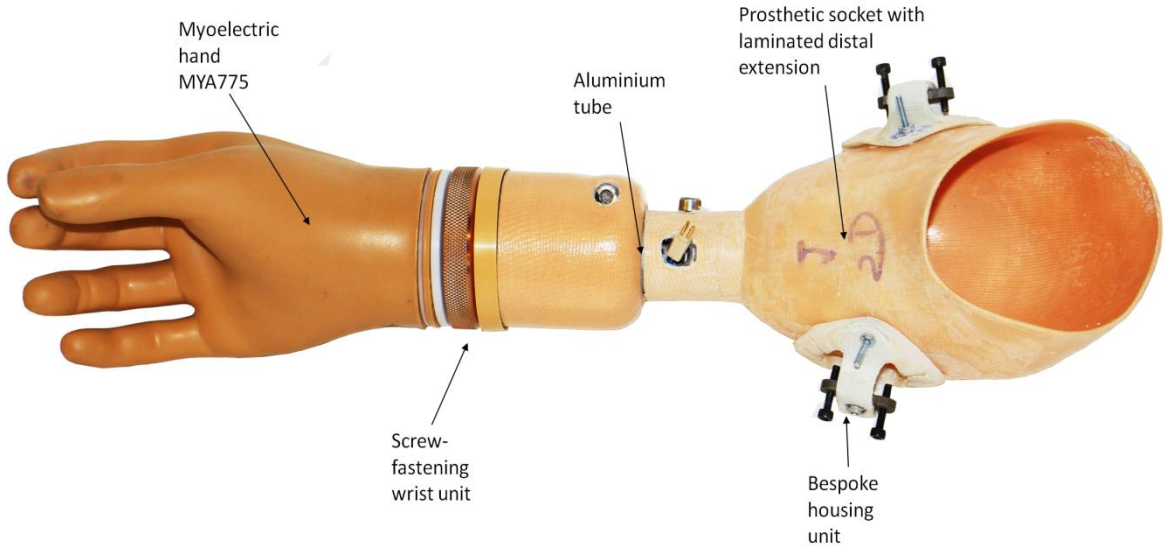


Figure 5.9: The bespoke modular prosthesis designed for the extended electrode housing study.

The myoelectric system used housed differential electrodes within the prosthetic socket using flexible locaters pre-manufactured into each end of the electrode. Standardisation was employed to limit the effects of any external factors associated with using different myoelectric socket arrangements. For the purposes of accurate assessment, each socket was capable of housing the electrodes in 3 rotational arrangements (**figure 5.8**). The functionality afforded to the prosthesis user with each of the three arrangements was assessed using the Southampton Hand Assessment Procedure (SHAP) (illustrated in fi**gure 5.10**).

Each socket fitting was adjusted to provide comfort for the prosthesis user. In addition, the gain or amplification setting was adjusted to meet the specific requirements of each subject.

Each subject was allowed to acclimatise to the bespoke prosthesis and practise using each electrode housing method prior to each assessment and to do this when acclimatising to the SHAP for at least 15 minutes prior to any assessment. In addition, each subject also undertook a period of acclimatisation with the SHAP on a previous visit to ensure they were able to complete the tasks required satisfactorily. During the main testing periods, three separate SHAP assessments were carried out for each electrode arrangement, by each subject.

The primary outcome measures were therefore the SHAP functionality scores obtained using the following test conditions:

- A prosthetic socket with the standard electrode housing with the electrode positioned in the assessed alignment position;
- The same socket with the bespoke electrode housing unit attached and with the electrode again in the assessed alignment position but adjusted using the plungers to improve the perceived contact security experienced between the skin and the electrode surface;
- The same socket with the bespoke electrode housing unit with the electrode rotated along its longitudinal axis by 25 degrees with the distal aspect of the electrode rotated 'nose downwards' compared to the assessed alignment position and again adjusted for perceived contact security;
- The same socket with the bespoke electrode housing unit with the electrode rotated along its longitudinal axis by 25 degrees with the distal aspect of the electrode rotated 'nose upwards' compared to the assessed alignment position and adjusted for perceived contact security.

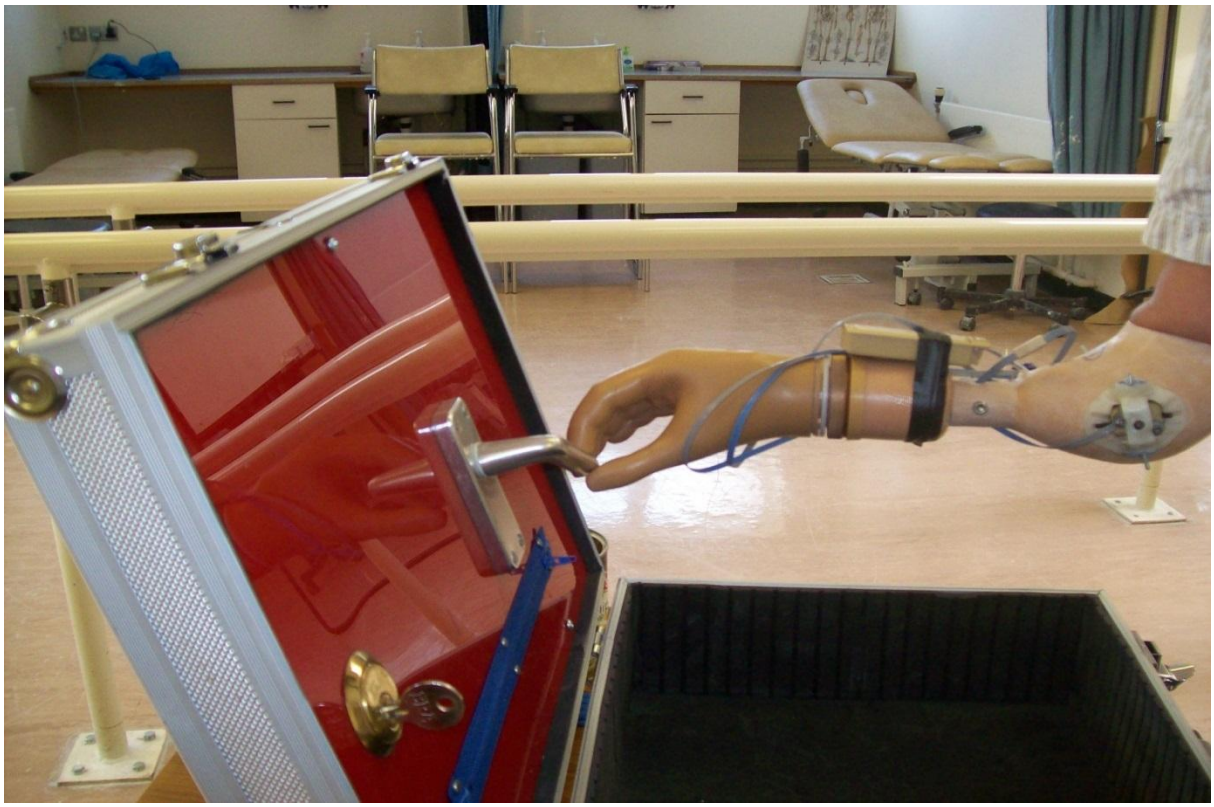


Figure 5.10: Subject 'B'' undertaking the SHAP using the prosthesis with a socket incorporating the electrode housing unit.

The arrangements were randomly switched between assessments to balance the effects of practise and improvement, in an identical manner that to that described in **chapter 4,** section 4.5. The SHAP assessment was carried out three times for each electrode arrangement, making a total of 12 overall assessments per prosthesis user.

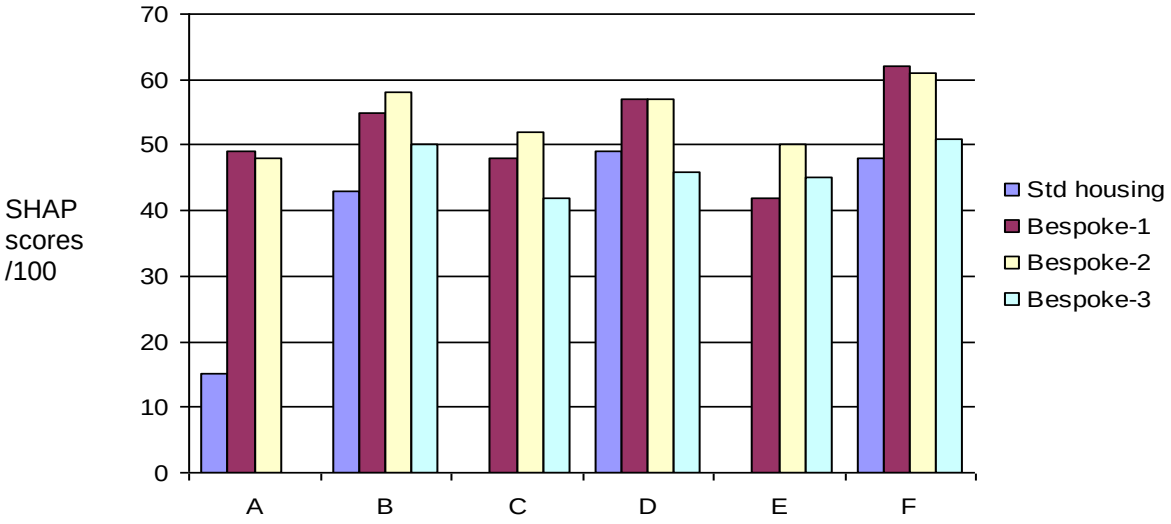
5.9 *Results*

5.91 *Overall functionality index assessment scores*

The combined scores for each assessment are recorded below (**table 5.2)** and presented graphically in **figure 5.11**.

User/score / **Electrode arrangement**	**SHAP functionality assessment score / 100**					
	A	**B**	**C**	**D**	**E**	**F**
Test condition 1: Standard housing	15	41	0	54	0	48
	25	45	0	46	0	49
	5	43	0	49	0	47
Mean score	**15**	**43**	**0**	**49**	**0**	**48**
Test condition 2: Bespoke (1)	53	56	49	57	40	59
	50	57	49	55	41	64
	44	53	46	59	44	63
Mean score	**49**	**55**	**48**	**57**	**42**	**62**
Test condition 3: Bespoke 2	49	59	50	59	51	60
	46	60	52	47	48	64
	49	55	54	55	51	59
Mean score	**48**	**58**	**52**	**57**	**50**	**61**
Test condition 4: Bespoke 3	0	49	43	47	51	50
	0	50	41	43	53	54
	0	51	42	48	51	48
Mean score	**0**	**50**	**42**	**46**	**45**	**51**

Table 5.2: Functionality scores from each SHAP assessment with respective electrode alignment positions (1), (2), (3) using the housing unit, and the standard socket housing (std).



Legend

Std = assessed alignment position by an experienced Prosthetist within standard housing

Bespoke-1 = assessed alignment position within bespoke electrode housing

Bespoke-2 = alignment rotated 25^0 'nose down', with respect to Bespoke 1, within the bespoke electrode housing

Bespoke-3 = alignment rotated 25^0 'nose up', with respect to Bespoke 1, within the bespoke electrode housing

Figure 5.11: Mean functionality scores from each SHAP assessment with respective electrode alignment positions (1), (2), (3) using the housing unit, and the standard socket housing (St).

Test Condition	Mean SHAP Value (all tests)
Test 1 Standard	26
Test 2 Bespoke 1.	52
Test 3: Bespoke2	54
Test 4: Bespoke 3	30

Test Condition	Mean SHAP Value (excluding zero values)
Test 1 Standard	39
Test 2 Bespoke 1.	52
Test 3: Bespoke2	54
Test 4: Bespoke 3	47

Table 5.3: Mean SHAP functionality index scores

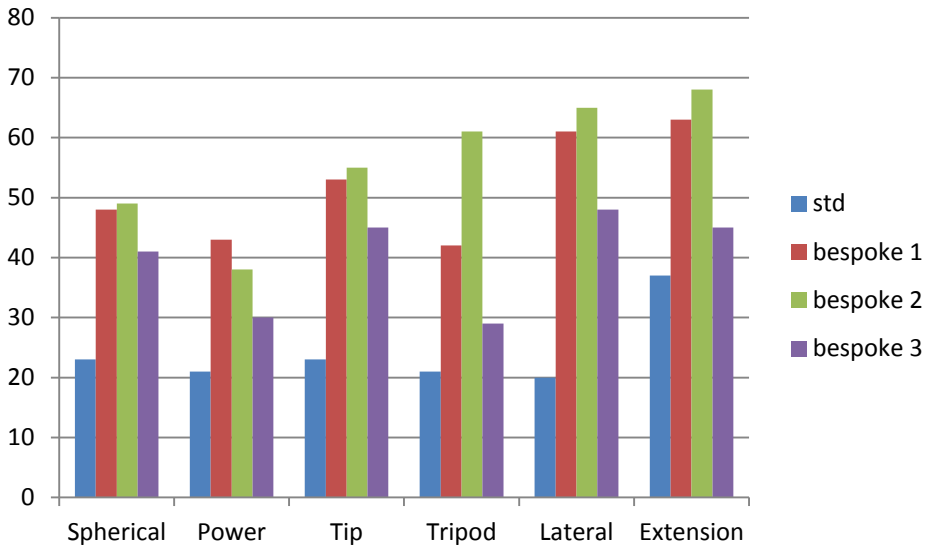
The mean maximum SHAP score when using the bespoke housing (where contact security could be adjusted) compared to the standard housing was significantly increased in all subjects by an average of 88%, where all scores were included. Where scores of 'zero' were excluded, this was still an increase of 32%.

A Friedman's repeated measures assessment, with post-hoc analysis was performed to assess the significance of the data; because the data is non-parametric and this is an analysis technique that is useful for repeated, small samples and related variables. This analysis showed a statistically significant difference in prosthesis functionality when using the different housing conditions at $p<0.001$, χ^2 (3) = 35.107. A post-hoc Wilcoxon signed rank test also found a significant difference between the functionality achieved using the standard housing and bespoke-1 and bespoke-2 respectively at $p<0.001$. Use of the bespoke-2 housing and bespoke-3 housing also proved to be functionally significant at $p<0.001$. Use of the bespoke-1 housing, when compared to the bespoke-2 housing and bespoke-3 housings respectively, was not significant at $p=0.035$. Additionally, functionality achieved via the use of the standard housing when compared to the use of the bespoke-3 housing was not significant at $p=0.060$.

5.9.2 *Individual grip type functionality assessment scores*

It was noted in **chapter 2;** section 2.2.1, that the human hand affords six different grip types. It was also noted, in **chapter 4;** section 4.4.2, that the SHAP quantifies these as part of its assessment scoring process.

As well as providing overall functionality scores for each user, the SHAP produced index of functionality scores for each of the grip types. The mean values for all these scores, for each test condition, are presented below in **figure 5.12**:



Legend

Std = assessed alignment position by an experienced Prosthetist within standard housing

Bespoke-1 = assessed alignment position within bespoke electrode housing

Bespoke-2 = alignment rotated 25^0 'nose down', with respect to Bespoke 1, within the bespoke electrode housing

Bespoke-3 = alignment rotated 25^0 'nose up', with respect to Bespoke 1, within the bespoke electrode housing

Figure 5.12: Mean hand grip type functionality scores from each SHAP assessment with respective bespoke alignment positions (1, 2, 3) using the bespoke housing unit, and the standard socket housing (Std).

Grip type	**Functionality index score/position**				**Mean**	**SD**
	Std.	Bespoke 1	Bespoke 2	Bespoke 3		
Spherical	23	48	49	41	**40**	**12.0**
Power	21	43	38	30	**33**	**9.6**
Tip	23	53	55	45	**44**	**14.7**
Tripod	21	42	61	29	**38**	**17.5**
Lateral	20	61	65	48	**49**	**20.3**
Extension	37	63	68	45	**53**	**15.1**
SD	**6.4**	**8.9**	**11.2**	**8.2**		

Table 5.4: Functionality index scores for each grip type, also showing overall mean scores for each grip type and appropriate Standard Deviations (SD) between housing positions, and between grip types.

The ‘power’ grip afforded the smallest mean functionality index score (score = 33), although variations between scores for the ‘power’ grip using different electrode positions were also the smallest (SD = 9.6). The ‘extension’ grip had the highest mean functionality index score (score = 53), followed by the ‘lateral’ grip (score = 49), although the ‘lateral’ grip also appeared to be the one most susceptible to change with regard to electrode position (SD = 20.3). The standard housing produced the lowest variation between grip scores (SD = 6.4) but this reduced substantially to only SD = 1.3, when the ‘extension’ grip score was removed from the calculation. These results show that different electrode housing and alignment positions will have varying levels of influence on the functionality of different grip types. A further study is required to investigate whether electrodes positioned within the standard housing reduce the available functionality of specific grip types.

The standard electrode housings rely on the Prosthetist carefully contouring the appropriate electrode site area onto the positive plaster model, but do not provide the finite levels of contact control that are provided by the bespoke housing unit tested in this study. Plastic or felt washers and elastic bands may subsequently be used on the outer surface of electrodes to enhance contact security in conjunction with standard housings, but this was not tested in this study. Additionally, these methods do little to ensure secure contact across the surface of the electrode and could actually disrupt this, if for example the electrode is able to pivot around the elastic band.

The variations demonstrate that a housing arrangement which enables alteration to electrode alignment would be of benefit to Prosthetists who are attempting to achieve maximum signal acquisition for the prosthesis user. Electrodes aligned in the bespoke 3 test condition (i.e. with the distal end of the electrode in a ‘nose up’ position with respect to the standard position) produced a significantly larger reduction in prosthesis functionality than electrodes aligned in the relative ‘nose down’ position. There were significant functionality score variations between the test conditions where the electrodes were rotated away from the assessed standard alignment position (i.e. bespoke 1 and bespoke 3), and also between bespoke 2 and bespoke 3, even though the contact security could be adjusted using the bespoke housing mechanism. For one subject, user ‘A’, electrodes in the bespoke 3 position proved unusable. This highlights the fact that even when connect security is enhanced, alignment of the electrode will still affect the functionality of the prosthesis, within what could be considered a reasonable practical alignment range.

It is therefore important to recognise these factors when determining electrode alignment, particularly as they can lead to a significant change in the resultant functionality of the prosthesis. It is also worth noting that these alignment positions may be altered if the transfers of alignment marks from the original negative cast taken by the Prosthetist are not accurate, or if the dummy housing slips during the manufacturing process.

The lack of electrode adjustment in the myoelectric control system contrasts with the evident adjustability of other types of prosthesis control. For example, in lower limb prostheses, prosthesis control source is usually reliant on the biomechanical relationship between the body's weight line and the ground reaction forces. By providing the correct alignment between the prosthesis components, the Prosthetist is able to provide the platform for effective control for the prosthesis user. For this reason, alignment devices and components within the prosthesis allow finite levels of adjustment, enabling suitable settings to be included prior to the delivery of the prosthesis, and at later dates should there be changes to the user's anatomy or requirements.

5.10 *Discussion*

The scores for the functionality index scores (**figures 5.11** and **5.12**) clearly indicate that the use of an independent, adjustable housing unit that offers increased contact security as perceived by the prosthesis user, can significantly improve myoelectric prosthesis functionality.

The variation in the results suggests that the most effective electrode site for signal acquisition is not easy to recognise, even for experienced Prosthetists. Simply positioning the electrode in line with the line of progression of the residual limb is not always the best way to achieve optimal signal results. The variations also suggest that a housing arrangement that enables electrode alignment alteration would benefit Prosthetists who are trying to achieve maximal signal acquisition for the prosthesis user. Significantly higher functionality index scores may be achieved using electrodes housed in specific alignment positions (i.e. as assessed or 'nose down') in the bespoke housing unit with respect to the standard housing unit.

The inclusion of modular systems, particularly in lower limb prosthetics, has greatly enhanced the adjustment available to Prosthetists when trying to ensure the natural gait,

comfort and function for prosthesis users. Even if original alignment or other discrepancies are present within a prosthesis, these may be altered and refined to provide suitable usability for the recipient. The availability of positional adjustments post-fitting for myoelectric prosthesis electrodes would appear to be much more limited. The implications of prosthesis user function and usage are no less relevant, as the effective control of a myoelectric prosthesis will ultimately determine its level of usage and potential rejection. Attempts to improve contact security through the use of roll-on sockets and 'snap fit' electrodes will meet the needs of some prosthesis users, but if the residual limb is not suitable for the application of a roll-on socket, or indeed if the user does not have the capacity or the willingness to wear one, then this will not be suitable. Many prosthesis users are children, who will have changing residual limb sizes and shapes-at present, meeting their exact needs may be challenging, even for the most experienced Prosthetists.

Having some adjustment available within an electrode housing system will provide the capacity for contact security to be enhanced within a relatively large socket. In addition, those users who have more proximal limb absence will benefit from local electrode adjustability, as current socket designs for these levels do not provide the snug fit that is achievable at the transradial level.

Experienced Prosthetists will be more able to recognise suitable electrode positions, but the relatively small number of myoelectric prosthesis users means that this experience will be limited even amongst those Prosthetists that are more specialised within upper limb prosthesis rehabilitation. More recently, the role of the upper limb Prosthetist has changed within the United Kingdom, from a more specialised role to one that is carried out in conjunction with lower limb prosthetics and even orthotics (see **Appendix E-** *The changing education of Prosthetists*). This role change has further reduced the levels of experience that many of those dealing with upper limb prosthesis users, including myoelectric users. Obtaining functional electrode positions may not be easy for those Prosthetists that will only be presented with a very limited number of myoelectric prostheses during their careers.

5.11 *Limitations and potential errors*

Although the bespoke housing unit was able to be moulded to each socket, the exact fit and contour was sometimes difficult to achieve. This could potentially affect the results, as the electrode may sit more securely on the socket wall in one of the positions with respect to

other positions if variations in contouring occur. This could therefore have influenced, albeit to a small degree, the functionality index scores that were achieved.

Heating and remoulding the bespoke housing unit also influenced the shape of the unit round the screw-thread fastenings and the semi-rigid rod locators. This again could alter the contact and security of the electrode in any of the positions within the housing unit. In addition, the standard housing system had to be assessed first, because it had to be removed and an aperture in the socket created to allow for the fitting of the bespoke housing unit. Despite the user subject having time to practice prior to each assessment, this could have influenced the results negatively with regard to the standard housing unit, albeit not to the degree that was seen within the data.

Despite these potential limitations, the significant variance in the results suggests that fitting a bespoke electrode housing unit can produce a significantly positive improvement to prosthesis functionality. In addition, variances within electrode alignment can influence prosthesis functionality when designated by Prosthetists who are not experienced with the assessment and fitting of myoelectric prostheses.

5.11 *Chapter summary*

The use of an adjustable housing unit which provided the facility to provide alignment and contact security variations demonstrated significant variances in prosthesis functionality compared to the commonly accepted clinical standard. The number of alignment variations was limited to three in this study, and the unit itself was fixed which restricted the capacity of the system to provide more clinical fitting. Nevertheless, despite these limitations, the unit was able to illustrate the changes in prospective functionality that may be recorded when even relatively small alignment alterations and contact security arrangement are provided.

As the clinical profile of the upper limb Prosthetist changes, and the capabilities of upper limb devices improve along with their costs, it is vital that every effort is made to ensure that adjustments are available for upper limb myoelectric prostheses that provide effective levels of electrode contact if the prosthesis user is to acquire the maximum benefit from their device.

Chapter 6:
An analysis of motion artefacts produced from the electrode / residual limb interface during movements associated with daily living activities

6.1 *Introduction*

In **chapter 2,** the process of myoelectric signal acquisition using differential electrodes was described and, more specifically, how motion artefacts could occur if the electrode's surface contacts moved or lifted with respect to the skin. **Chapter 2** also highlighted how the production of motion artifacts that can mimic the myoelectric signal and impede genuine activation signals could potentially disrupt myoelectric hand control and activation.

In **chapter 3**, a correlation between relative socket and electrode tightness and disrupted control of the myoelectric hand, including false and unwanted activation of the myoelectric hand, was established. However, no specific link between the production of motion artifacts and control disruptions was possible, as other factors could also lead to activation disruption of the myoelectric hand. These include mechanical and technical failures of the hand, low battery power, electrical interference, and the users' inability to produce and regulate the myoelectric signals.

Chapter 3 also indicated that myoelectric prosthesis usage patterns resembled those of cosmetic, rather than functional, prostheses, indicating that certain functional activities may preclude myoelectric prosthesis usage. However, no specific correlation between definitive daily activities and control disruptions were identifiable.

The functionality assessments performed as part of the investigative processes within **chapters 4 and 5** illustrated key variations in functionality that were available from different electrode housings and positions. The basis of the SHAP is the structured use of a number of ADLs, which relate a numerical outcome with respect to functionality. However, the exact link between the movements of the natural upper limb, and the residual limb, associated with performing these or other ADLs with respect to the production of motion artifacts has not yet been corroborated. If functional activities are restricted because of problems with myoelectric hand activation and control, caused by the production of motion artifacts during daily activities, then an assessment that can correlate the production of motion artifacts with

specific daily living activities is required. Consequently, this type of analysis will form the basis of this chapter.

6.2 *Movements and analysis associated with the activities of daily living*

The natural upper limb is a coordinated, multi-articulated system, where the combined motion of each joint and element contributes to the overall functional capability (32). Its intricacy of movement is clearly demonstrated when attempts are made to replicate its many movement capabilities. Perry and Rosen (2006) produced a 7 degree of freedom upper limb robotic arm, which mirrored 99% of the ranges of motion required to perform daily living activities, but took considerable time and effort to produce (254). Acquiring knowledge of the upper limb joints and its design are essential for prostheses replacement; although upper limb activities are many and varied, studies into these movements are far less extensive than those that have been conducted for lower limb gait evaluations (63).

Historically, upper limb movement analysis has investigated specific movements that relate to daily living activities, particularly where the focus has been on prosthetic rehabilitation. Gilad (1983) performed micro-motion analysis with both able-bodied and prosthesis user subjects using ‘reach’, ‘grasp’, ‘movement’ and ‘positional’ motion evaluation elements (255). A task board was employed, in conjunction with frame-by-frame video analysis. Gilad also found that prosthesis users employed compensatory movements to achieve tasks, with movements of the back and shoulder used more predominantly than elbow movements (255).

In 1995, Doeringer & Hogan assessed the movement performance and output impedance of six transhumeral, prosthesis users (256). The subjects were observed performing ADL-based tasks, such as pointing, more slowly, and with less accuracy, with the prosthesis when compared to the same movements using the sound, natural limb (256). The body-powered prostheses used by the subjects were shown to be more consistent with normal usage patterns and ‘impedance to usage’ than myoelectric prostheses used by the same subjects. Although the act of ‘pointing’ was used as part of the assessment criteria, it was said that even quantifying this relatively simple movement was very difficult with regard to the trajectories of ADLs, due to the intricate balance and changeable nature of the various joint angles associated with the activity (256).

In 1998, Gilin used a single-subject study, again with a transhumeral level of limb absence and body-powered prosthesis, to evaluate daily living activities and movements associated with prosthesis wearing and the effect of limb absence (257). ADL screening, using a list of ADLs on a paper form, was used to assess the usefulness of the prosthesis when performing tasks including eating, working at a desk, housekeeping and general activities. The motion of the shoulder joint was also manually measured using a goniometer; the available shoulder flexion (135°), and abduction (140°), was lower than the standard figures quoted in **chapter 2, figure 2.3a,** although the other ranges of motion appeared to be at least on par with these standard ranges.

Murray and Johnson (2004) collected data from 10 male subjects using specific upper limb activities which included 'reaching', 'raising objects' and 'hand to mouth movements' (63). The subjects were asked to perform these activities at comfortable speeds during the assessment process, and a maximum additional load of 500g was added during some of the activities. Raising a large block produced the most forces in the joints, the amount of which was calculated using rigid body kinematics and inverse dynamics, with the associated movements being assessed using a system of cameras and reflective markers.

In 2008, Carey and Highsmith used a mixture of transradial prosthesis users and able-bodied subjects to investigate five different ADLs, which were 'reaching', 'drinking from a cup', 'opening a door', 'turning a steering wheel' and 'lifting a box' (32). Again, a system of cameras and reflective markers were used to acquire the data, and a bespoke testing apparatus was used to ensure that the tasks were employed effectively. A particular analysis was made of the movement pathways that were employed by each subject during the tasks, with the natural pathway (able-bodied subjects) being contrasted with the pathways used by the transradial prosthesis users. Greater motion around the torso was noted for the prosthesis user subjects with respect to the able-bodied subjects, and compensatory movements by the prosthesis user subjects using the elbow also occurred during each of the activities (32).

Bouwsema et al (2010) used a mixture of transradial and transhumeral prosthesis users and able-bodied subjects to compare forearm trajectories, using a similar camera and reflective marker-based methodology to that used by Carey and Highsmith (2008) (32, 258). Pointing and grasping activities were employed during this study, since it was stated that these had been used more often in previous studies. Forearm trajectories were seen to be

smoother for transradial prosthesis users than transhumeral prosthesis users, with grasp times being recorded as being higher for transhumeral users also (258). The authors also stated that the way a prosthesis used in ADLs has received little attention via investigative practice (258).

Again, in 2010, Butler et al observed 'reach and grasp' activities, as performed by children, the majority (90%) being able bodied, with the remaining subjects presenting with Cerebral Palsy (259). The authors' stated that these ('reach and grasp' type) activities are essential for ADL completion and daily living. Quantifying these types of tests however, is very problematic, and activity outcomes, rather than the specific movement pathway elements associated with the movements, are more useful to acquire (259).

Although the methods of data collection have varied over recent years, the assessments have all attempted to classify upper limb movements and trajectories in terms of ADLs. Specific evaluations focusing on pure joint angles have been less important than the need to quantify upper limb movements in relatable trajectories that are relatively simple and repeatable, but are representative of daily movements and activities. As a result, this study used activities and movements that correlate to ADLs, and outcomes, rather than specific joint angles and other intricate data, which is relatively irrelevant to the aims of this study.

6.3 *Relative motion between the socket and the residual limb*

Relative motion between the myoelectric socket and the residual limb is clearly key to the production of motion artifacts, but is relatively common within standard prosthetic sockets at virtually all levels of limb absence (71, 116). Small displacements between the skin and the inner surface of the socket often occur with most socket types, and anecdotal evidence suggests that some prosthesis users prefer a slighter looser fit, particularly if the skin is sensitive or fragile. Cotton or woolly socks can be worn over the residual limb, cushioning the effects of loads incurred during prosthesis usage. However, excessive movement, or 'pistoning', can lead to uncomfortable skin abrasions and a lack of proprioceptive feedback (114). The development of roll-on sockets, such as the ICEROSS (see **chapter 2**), has been made to improve suspension and reduce these movements (131).

Motion between the socket and the residual limb in upper limb prostheses usually involves smaller loads than would be recorded in lower limb prostheses, since upper limb

prosthesis usage is not subject to the relatively large ground reaction forces associated with gait (110, 115). However, even though the loads on the prosthesis will be smaller, the range of upper limb movements that may occur during normal daily living are extensive, depending on the individual involved and their own daily requirements, activities and occupation (see **chapter 2**). If the prosthesis is light, and / or the suspension is effective, then motion between the residual limb and the socket should be minimised (23, 104).

Depending on the prosthesis type, either the self-suspending socket or the harness should maintain the upper limb prosthesis in the correct anatomical position during prosthesis motion (104). As most transradial prostheses are light cosmetic types, they will normally only exert small loads on the interface between the residual limb and the socket (102). Therefore, motion between the socket and the residual limb is unlikely to be significant for wearers of cosmetic prostheses. In addition, even if slight movements between the residual limb and the socket do occur, these should have little impact on the effectiveness of the cosmetic prosthesis. The small forces generated within the socket mean that skin abrasions are unlikely, and even if the residual limb is sensitive (often following a trauma-related amputation, see **chapter 2**) the use of socks to cushion the interface will not hinder prosthesis usage (116). Cosmetic prostheses remain the most popular choice for the upper limb prosthesis wearer, despite their obvious limitations (6, 14).

Similarly, as previously noted in **chapter 2**, the socket in body-powered prostheses plays no functional role in prosthesis activation or functional usage. The harness will absorb most of the forces generated during prosthesis usage, as well as ensuring that the prosthesis components remain in the correct relative anatomical positions (256).

For myoelectric prosthesis users, the problem with relative movement between the socket and the residual limb becomes more significant, primarily because of the reasons, such as electrode motion and lift, discussed in **chapter 2**. However, anecdotal evidence suggests that most sockets employed in clinical use for myoelectric prostheses are very similar to those employed for cosmetic prostheses and body-powered prostheses. Traditionally, it is the length of the residual limb and the composition of the remaining tissues within the residual limb that determine the transradial socket type for each prosthesis user (28, 37). Socket tightness may be increased to accommodate the heavier components fitted to a myoelectric prosthesis in an attempt to reduce the slippage that may occur between the residual limb and the socket at

their interface. However, the prosthesis user may not accept a tighter fit and may wish to revert to a standard, looser fitting, or wish to wear socks, particularly if the residual limb is unable to tolerate greater loads e.g. because of tissue sensitivity.

6.3.1 *The effect of load variations on socket movement during prosthesis usage*

Two main factors will influence the effective load acting on the socket during daily living activities:

1. The weight of the prosthesis itself, particularly the prosthetic hand;
2. The effective load being moved or carried by the prosthesis during the activity.

The weight of the hand will be particularly significant, since this will act at the distal end of the prosthesis, and will therefore have a larger lever effect on the socket. Myoelectric hands are significantly heavier than cosmetic hands, even though the socket types are similar (118, 119). Numerous surveys have highlighted prosthesis users' wishes for lighter hands and prosthesis components, and prosthesis manufacturers have tried to accommodate these wishes into current designs (12, 14, 15, 51, 224). However, the need for greater functional and technical capability has also contributed to the necessity for a relatively heavy myoelectric hand (118, 119).

The length of the residual limb will also affect the load acting on the socket (4). Shorter residual limbs will be more susceptible to high loads due to the extended lever effect. Soft, fleshy residual limbs will also be prone to movement between the residual limb and the socket, since these will inherently provide a looser interface with the socket (42, 125). Anecdotal evidence suggest that these factors may have inhibited the prescription of myoelectric prostheses to those potential users who do not have either long or relatively firm residual limbs.

Loads moving the myoelectric prosthesis socket with respect to the skin can potentially affect the functional capabilities of the differential electrodes. This part of the study evaluates the motion artifacts that may occur in commonly prescribed socket types currently used in clinical prescription in the UK for transradial prostheses and discusses the potential effect of these artifacts on prosthesis functionality. Standard sockets and componentry (listed below) were incorporated within a bespoke modular prosthesis that

enabled sockets to be interchanged between users, thereby maintaining procedural consistency. Each prosthesis user undertook a series of movements representing common activities of daily living, using various loads to simulate either an item being carried or a heavier terminal device being worn. The signal generated at the interface of the electrode and the residual limbs were recorded using the 'Myoboy' prosthetic myoelectric assessment system.

The following methodology describes in detail the above procedure, the equipment used and the processes involved to complete this investigation.

6.4 *Methodology*

Prior to the commencement of this part of the study, ethical approval was sought and provided by the relevant National COREC ethical committee following the submission of the requisite protocol and other relevant material plus the relevant local ethical approval. Following this, five transradial prosthesis users with experience of using myoelectric control were recruited for the study, from the University of Salford's professional patient database. The selection and recruitment criteria are described in section 4.4, **chapter 4**. The selection procedure is outlined in section 4.4, **chapter 4**. Relevant ethical approval documents, together with a patient consent form, can be viewed in **Appendix B**-*Ethical approval and related documents.* Associated documents with this investigation also included a patient information sheet, patient consent form and an investigation protocol adapted from those available within **Appendix A**-*Questionnaires and Questionnaire development*, with alterations provided detailing the differences in the analysis regime.

This investigation evaluated specific factors that could potentially produce motion between the socket and the residual limb. These factors are:

1) Prosthesis loading: the weight of the prosthesis, plus any other load that is carried or lifted by the prosthesis;
2) Prosthesis/ upper limb movement: the *approximate* movement of the limb and prosthesis during the activity.

For these factors to be evaluated accurately and consistently, a prosthesis that allowed the interchange of different sockets within a standard arrangement was required. In addition,

this prosthesis needed to be adaptable in terms of its length and be able to permit the addition of small loads where appropriate. As stated previously (see **chapter 3**), most upper limb prostheses are exoskeletal, with the socket laminated within the prosthetic forearm for transradial prostheses. This arrangement does not allow socket interchange or length alteration once the prosthesis is manufactured. Consequently, a standard exoskeletal prosthesis was not suitable for the requirements of this study.

Unlike upper limb prostheses, the vast majority of lower limb prostheses are endoskeletal. Endoskeletal prostheses permit the type of adaptations and alterations as listed above, although there are few upper limb endoskeletal prostheses currently provided and these are usually light cosmetic types primarily developed for more proximal levels of limb absence (see **chapter 1**). A suitable prosthesis for this study would therefore need to be endoskeletal, but suitably robust to permit the attachment of a relatively heavy myoelectric hand. The production of a bespoke prosthesis arrangement was described in **chapter 5** and this prosthesis would again be employed within this part of the study.

Each socket fitting was adjusted to provide optimum comfort for the prosthesis user. In addition, the gain or amplification setting was adjusted to meet the specific requirements of each subject.

6.5 *Upper arm movements and analysis*

Selecting the appropriate movements that would represent the common upper limb prosthesis motions most likely to affect socket slippage was obviously crucial to this study. Inter-rating and Intra-rating repeatability of these movements was also essential if accurate data was to be obtained regarding socket motion with respect to the residual limb (260).

In section 6.2, it was shown that previous studies had incorporated ADLs as the basis of upper limb and upper limb prosthesis movement and trajectory analysis. For accuracy, relevance and validity, this investigation employed a similar strategy, using repeatable, relatively straightforward movements that were related to the activities of daily living, and reflected and represented natural actions used to complete normal daily tasks.

The act of ‘reaching’ was used extensively in previous studies, and would also be used as part of this assessment. Reaching is incorporated in many daily activities, and can be used for example in picking an object up from a position in front of the subject.

Reaching was a movement activity that was also employed in a series of assessments by Halswanter et al (2004), who determined movement trajectories and comparative subject assessments during the completion of ADLs in normal subjects (261). In addition to ‘reaching’, Halswanter et al also employed two other movement activities; a ‘hand to shoulder’ movement activity and a ‘hand to hip pocket’ movement activity. The ‘hand to shoulder’ activity represented the acts of eating, drinking and putting objects to the mouth, activities also noted by separate authors conducting similar movement assessments as related in section 6.2.

The ‘hand to hip pocket’ activity was interesting, since it wasn’t relayed in other literature. However, the ‘hand to hip pocket’ movement activity did represent movements relating to reaching behind the subject, to the back pocket for a wallet, for example, and would provide evidence of a quite distinct movement pattern to the first two activities. For these reasons, the three activities used by Halswanter et al (2004) would be used within this study. The subject, whilst remaining seated, was asked to position the bespoke prosthesis in a series of pre-selected positions as described by Halswanter et al.

Figure 6.1 illustrates subject ‘A’ in the starting seated position which preceded all the movements that would be undertaken.

Figures 6.2 – 6.4 illustrates subject ‘A’ with the bespoke prosthesis in the respective movement completion points.

Figure 6.1: Subject ‘A’, in the seated, starting position for all movement activities.

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Figure 6.2 Subject ‘A’, employing the ‘reaching’ movement as described below.

Movement activity 1: Reaching

Description: The subject raises the index finger of their prosthesis directly in front of them to a point parallel to their eye line.

Relevance to ADLs: This task represents activities in front of the body, such as picking an object up from a shelf.

Figure 6.3 Subject ‘A’, employing the ‘hand to shoulder’ movement as described below.

Movement activity 2: Hand to sound side shoulder

Description: The subject touches their sound side shoulder with the tip of the prosthesis’ index finger.

Relevance to ADLs: This task represents all activities near to or across the sound side shoulder, e.g. eating or zipping up a jacket.

Figure 6.4: Subject ‘A’, employing the ‘hand to hip pocket’ movement as described below.

Movement activity 3: Hand to hip pocket

Description: The subject places the prosthesis index finger on the affected side hip pocket.

Relevance to ADLs: This task represents all activities that involve reaching behind, for example taking a wallet from the back pocket, or scratching the back.

In accordance with the procedure previously described by Halswanter et al (2004), the subject would be seated whilst the movements associated with daily living were being performed, except for the 'hand to hip pocket' activity, where the subject would sit up slightly in order to complete the motion with the relatively more cumbersome prosthesis.

The complete assessment therefore includes a comprehensive movement analysis applicable to the research criteria that provides a correlation between prosthesis movement and the production of motion artefacts. The series of movements chosen should replicate a range of daily living activities undertaken during prosthesis usage. The results would indicate if undertaking these activities caused significant relative motion to occur between the electrode surfaces and the residual limb resulting in the production of motion artifacts large enough to affect prehensor activation.

In addition to investigating the effects upper limb movement on the production of motion artifacts, an analysis of the effect of increasing prosthesis loading during each movement was also undertaken. In many daily living activities, objects are often lifted and carried, increasing the potential for the socket to become displaced during the activity. For this reason, an analysis comparing the effect of selected loads appropriate to daily living would be undertaken. The following section identifies suitable loads that may be employed for this part of the study.

6.6 *Loading variance analysis*

Initially, the employment of small steel weights attached to the prosthesis was the preferred method of adjusting the load during motion. However, acquiring weights that could fit the tubular structure was problematic and the attachment was found to be relatively crude. In addition, the weights would be located around the central forearm section, around the tube, and not around the hand. This would obviously not be comparable to the effect of loads lifted during normal usage.

Other options that were considered included the use of spring or force gauges, attached to fixed positions in the working vicinity of the prosthesis user. These had the advantage of being able to provide various loads that would resist each subject's movement, and not simply provide a fixed load that may be unsuitably heavy for some of the subjects. However, maintaining these gauges in the correct position or diametrically opposed to the

correct plane of motion during usage was problematic and inconsistent, and did not provide the degree of analysis that would be required for accurate and relevant data to be acquired.

The chosen option was the employment of pulleys attached to light loads that allowed selective and accurate loading to be administered during each movement. Pulleys could be obtained that would offer the attachment of small, varying loads and thereby allow for an accurate analysis to be undertaken during each motion. The use of pulleys allowed the subject to exert a force during motion that was suitable for the characteristics of their residual limb and their general upper limb strength and capability. The pulley(s) could be positioned along the axis of each of the 3 planes being assessed, thus providing consistency in each of the planar evaluations.

Pulleys can be obtained in a range of sizes and attachments, making them flexible enough for the requirements of this study, and would allow for the addition of very small loads that could be accurately calculated (only relatively small loads would need to be applied, since these would reflect more normal, natural tasks). The movement flexibility of the pulley system meant that each pulley could be secured in a position which would diametrically oppose the motion. The pulley(s) would need to be secured to a bespoke apparatus that was both stable and movable, thereby allowing the subject to move the prosthesis under the respective load against a fixed position. The construction of a suitable pulley apparatus is described in the section 6.7.

The loads employed would have to be within a range that could be considered as consistent with normal activities. In addition, the chosen loads would need to reflect the differences in strength that may reasonably exist when considering a range of transradial prosthesis users from different age groups, genders and physical capabilities. The chosen loads must also be applicable to the effects of the shorter lever arm (the residual limb would be shorter than the natural limb) plus the inherent loading imparted by the prosthesis itself, particularly the relatively heavy myoelectric hand.

Anglin and Wyss (2000) describe an investigation based on the activities of daily living associated with lifting, and use a 5Kg box and 10Kg suitcase as part of their study (262). They also state that an average lifting mass that approximates to 3% of the subject's bodyweight may be appropriate for investigations into these types of activities (262).

However, these figures relate to healthy, able-bodied subjects and not prosthesis users; for the reasons stated earlier, therefore, a reduction in these values would be required.

User comfort was always paramount when considering the experimental usage and value of the loads that would be employed. Cutti et al (2007) describes the loading of a transhumeral prosthesis with loads of up to 3Kg with various movements being undertaken by the single-subject prosthesis user (263). However, at loads above 1Kg, variations in elbow extension and flexion were noted from the anatomical 'norm'. It was therefore decided that loads of up to 1Kg would only be used with the subjects involved with the study, which included those from a variety of ages, backgrounds and capabilities. Choosing relatively low loads would provide the means for all the subjects to undertake the activities safely and in relative comfort. The loads would be incorporated within a bespoke pulley system which is described below.

6.6.1 *The bespoke pulley system*

The pulley system apparatus (from this point referred to simply as 'the apparatus') employed would require a rigid enough construction to safely withstand the movement of the loads but remain light enough to be relatively mobile, since its position may need to change with respect to the prosthesis user for the different movement patterns that required investigation. The dimensions of the apparatus would have to suit a subject sat at a chair performing the motions as described in the previous sections, and would have to allow smooth and continuous movement of the loads throughout the motions as described. The apparatus would also require the pulleys to be attached in an efficient and user-friendly manner.

Initially, a series of pulleys were purchased, which would be suitable for working with the loads as described in section 6.4. The chosen pulleys were of a light, plastic construction ('Nasco' pulley models SB23793M, SB16150M) exhibiting movements with low friction via a simple nylon cord which could be simply tied to each of the loads.

For ease of the attachment of the pulleys, a wooden frame was chosen, and is detailed in **figure 6.5** (below):

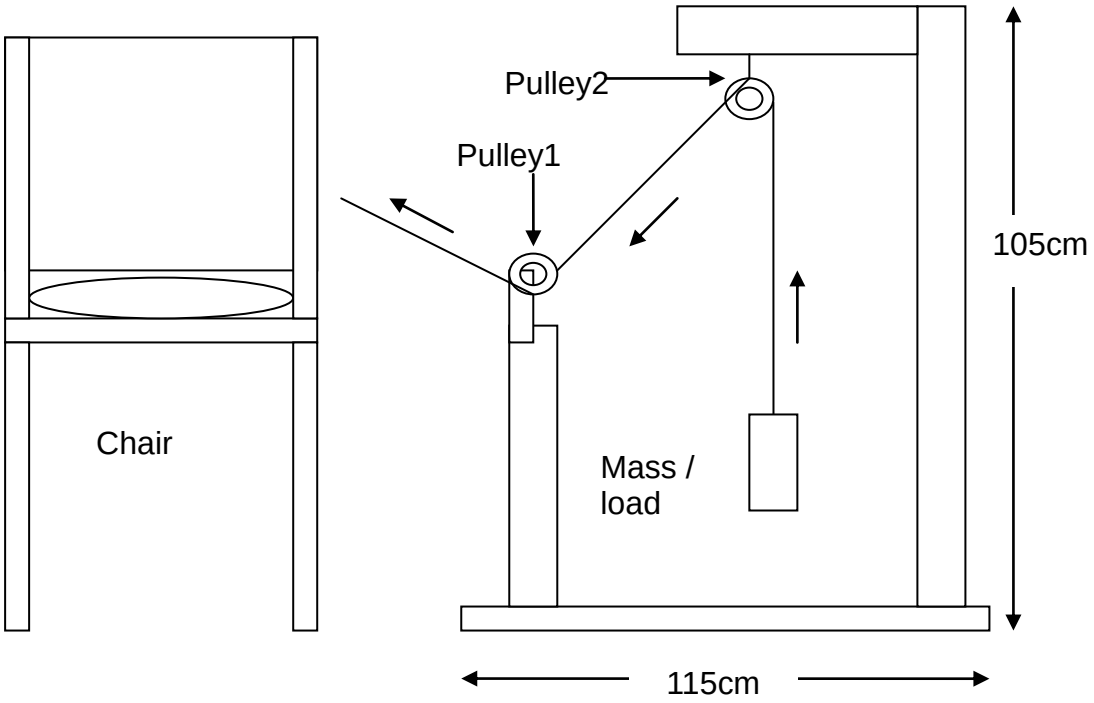

Figure 6.5: The pulley apparatus designed for the assessment within chapter 6

The design in **figure 6.5** was chosen for the following reasons:

1) The use of 2 pulleys, one set up relatively low, near to the subject, one relatively high, further from the subject, would permit the ranges of motion applicable for the study without the load impacting on the horizontal support post of the pulley system or onto the pulley itself.

2) The use of a relatively low pulley positioned close to the user would enable an accurate transmission of the load to occur without excessive distance between the pulley and the user (a greater distance could allow the pulley cord to become dislodged from the pulley during use).

3) Using a dual arrangement for the pulleys, with respect to simply using one, taller post with a relatively high pulley system attached, theoretically distributed the stresses on the apparatus more efficiently and therefore enabled the loads to be transmitted safely without the apparatus becoming damaged or broken during use.

The apparatus was constructed from wooden posts, secured to a flat wooden board using metal plates and wood screws, manufactured into the lengths as shown. The height of the posts corresponded to a suitable working height when situated close to a subject seated in a chair, without armrests, at a standard height. The pulleys were anchored as shown below, and were trialled before use to ensure that simple and effective operation was available.

The height of the pulley apparatus, and more specifically the distance between 'pulley 2' (see **figure 6.5**) and the resting height of the attached load(s), was constructed to allow enough room for the maximum movement distance that the load would conceivably be moved during any of the three movements. This distance corresponded to the distance that the palm of the hand (chosen as the most suitable attachment point for the loads) would travel from resting on the knee (the original starting point for all three movements chosen within the analysis) to its end respective end position e.g. at the sound side shoulder.

The author was considerably taller (1.86m) than any of the subjects that were to be used within the study. This was identified during the initial assessment process. Therefore, the distance travelled by the author's arm could be identified as a reasonable maximum amongst all the subjects. Measurements were therefore established that identified the distances travelled by the author's hand during each of the movements as specified. The distances measured are shown below in **table 6.1**:

Movement	**Maximum Distance travelled by the palm of the hand during initial assessment (cm)**
Reach	70
Hand to shoulder	66
Hand to hip pocket	62

Table 6.1: Distances travelled by the author's palm of the hand during each specified movement.

The minimum hand travel distance allowed with the bespoke pulley apparatus therefore needed to be 70cm. Therefore, the frame was constructed allowing a load-travelling

distance of 75cm, allowing for a small factor of safety within the arrangement (see **figure 6.4**, and **figure 6.6** (below)):

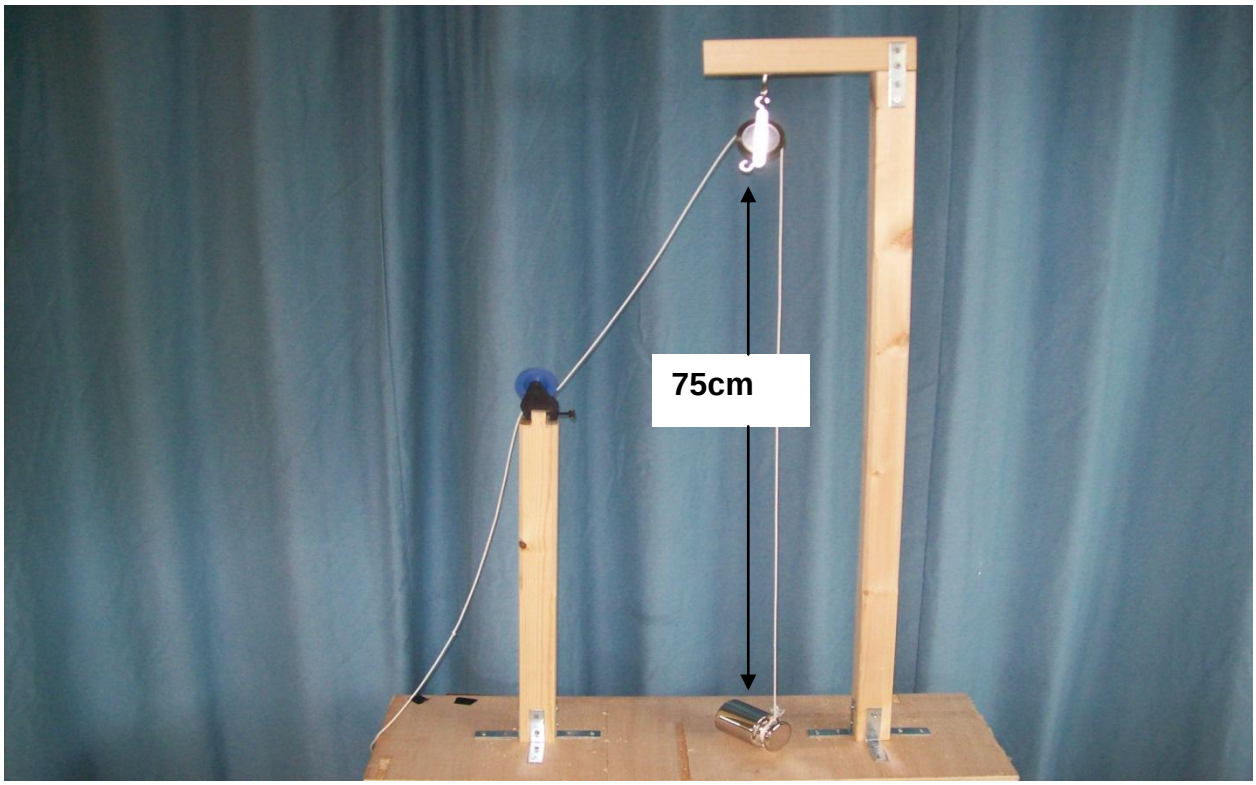

Figure 6.6: Pulley anchorage and maximum allowed travelling distance of the load (author's own image).

6.7 *Speed of upper limb movement analysis*

Movement between the socket and the residual limb evaluated under each method of loading, i.e. no load, 500g load, and 1Kg load attached to pulley, would be evaluated. The user would perform the complete movements as described at a comfortable pace. A total of 10 movements were chosen, to provide a reasonable data base for analysis without compromising the comfort of the prosthesis user. If required, the number of movements made during a minute would be calculated as a reps/minute calculation in each case, if there was clearly observable variance between subjects.

This analysis also required a system to record any myoelectric signals that were produced during each respective motion. This part of the data capture was provided by the 'Myoboy' prosthetic assessment system, which is detailed below.

6.8 *The 'Myoboy' prosthetic assessment system*

The 'Myoboy' prosthetic assessment system (model number757M11), is manufactured by world-renowned Prosthetic and Orthotic rehabilitation company Otto Bock, and is widely used in clinics across the UK and Internationally (264). It provides a clear, visual identification of the myoelectric signals produced within a socket or other connection to the skin via a software package that is easily uploaded on to a laptop or other computer. The myoelectric signals may be viewed as spikes of electrical activity on the computer screen, and the visual analysis provides both a timing cycle and signal intensity scale (in micro-volts) which enables the assessor to evaluate both the size and duration of any signal that is acquired. Each signal acquisition assessment may be recorded and replayed for later use, making the 'Myoboy' system ideal for the purposes of this study where numerous applications required independent signal capture and recording.

The 'Myoboy' assessment system provides a clear, visual threshold level that corresponds to the signal strength that would be require do activate the prehensor or myoelectric hand. Consequently, the assessor may note the points at which this threshold is met or exceeded, and hence record the instances at which false prehensor or hand activation would take place.

'Myoboy' is compatible with standard myoelectric electrodes of the type employed during this study. It simply connects to the electrodes in the same manner as the myoelectric hand. In this way, the dynamics of the assessment are no different from those that would be employed during standard prosthesis usage. The 'Myoboy' will acquire the same myoelectric signals in the same format as the myoelectric hand, but is able to provide detailed data on the strength and duration of each signal (see **figure 6.7**).

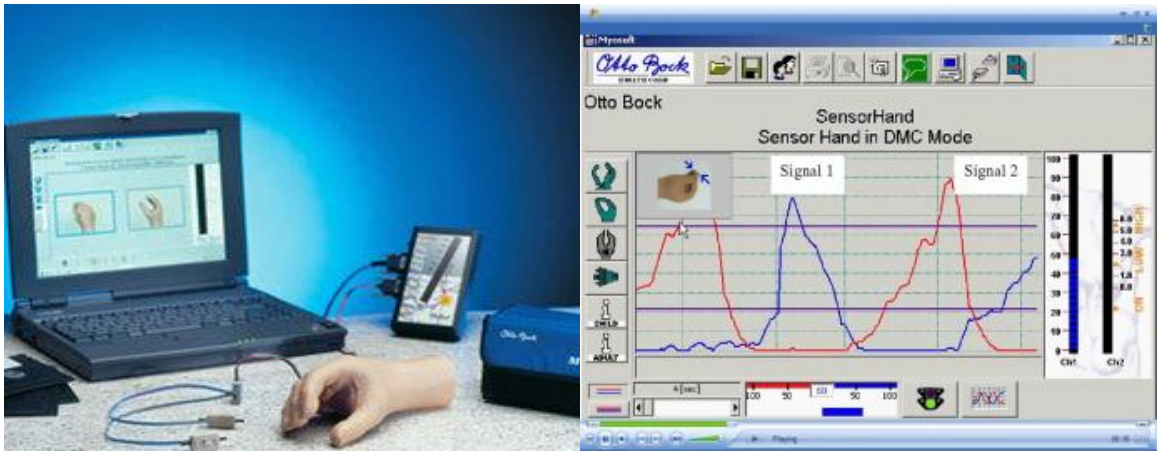

Figure 6.7: The 'Myoboy' assessment system (265).

6.9 *The Preliminary pilot study*

A preliminary pilot study was undertaken prior to the main investigation involving prosthesis users, primarily to clarify that the apparatus was indeed suitable for the purposes of the signal acquisition. The preliminary socket was used successfully in **chapter 4**. The preliminary socket is pictured below, in **figure 6.8** and resembles a 'North-western supracondylar' socket (37) (see also **chapter 2**). The socket was assessed as both comfortable and well-fitting prior to the commencement of the pilot study.

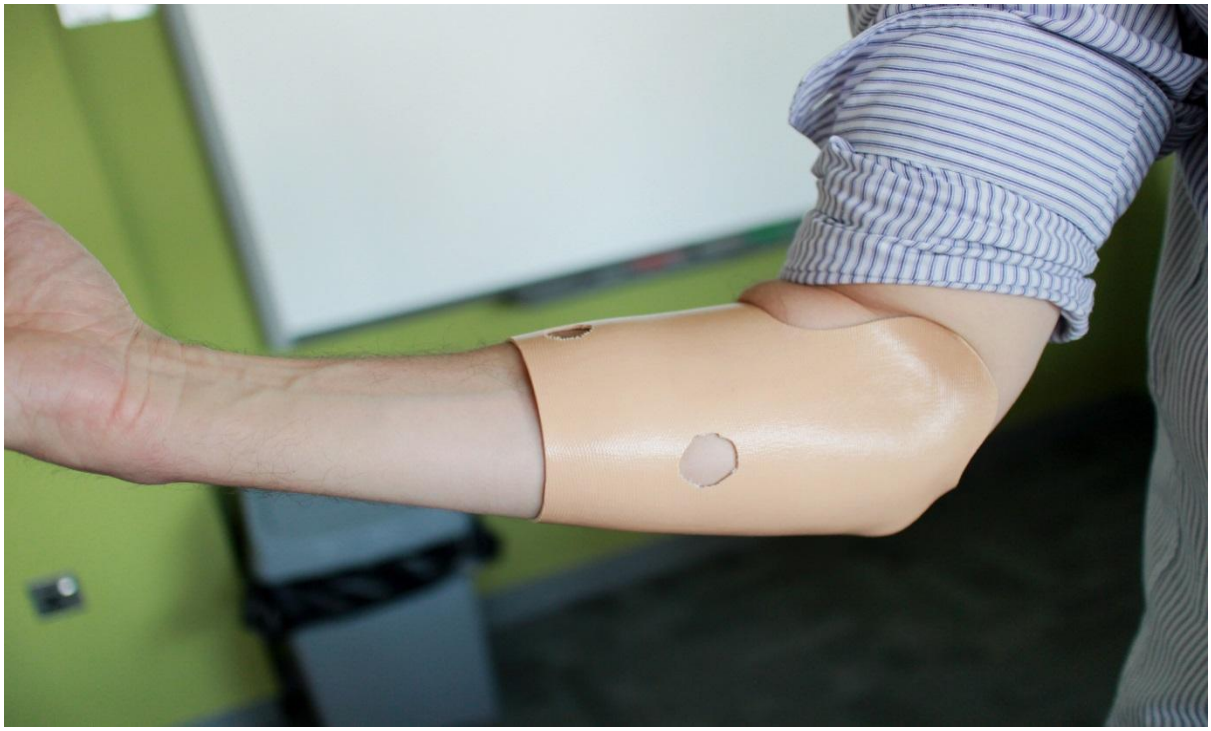

Figure 6.8: The Preliminary socket.

The preliminary socket had electrode positions created in the following areas:

1) Over the most prominent area of the *wrist extensors* muscle belly for the electrode used for the 'open prehensor' function;
2) Over the most prominent area of the *wrist flexors* muscle belly for the electrode used for the 'close prehensor' function.

Positions (1) and (2) represented the electrode sites where the myoelectric electrodes would normally be located. The preliminary socket enabled the author to apply loads to its distal end via an attachment screw, with the pulley cord attached to this prior to movement analysis. Through this arrangement, the author was able to assess the suitability of the three movement activities as stipulated in section 6.6 for the assessment of the signal responses via the 'Myoboy' data. Furthermore, the travelling distances of the associated electrode cables and attachments could be reviewed during the preliminary socket assessment review, to ensure that these were not displaced during each activity and to ensure that the system was placed in the relevant position in relation to the prospective subject(s).

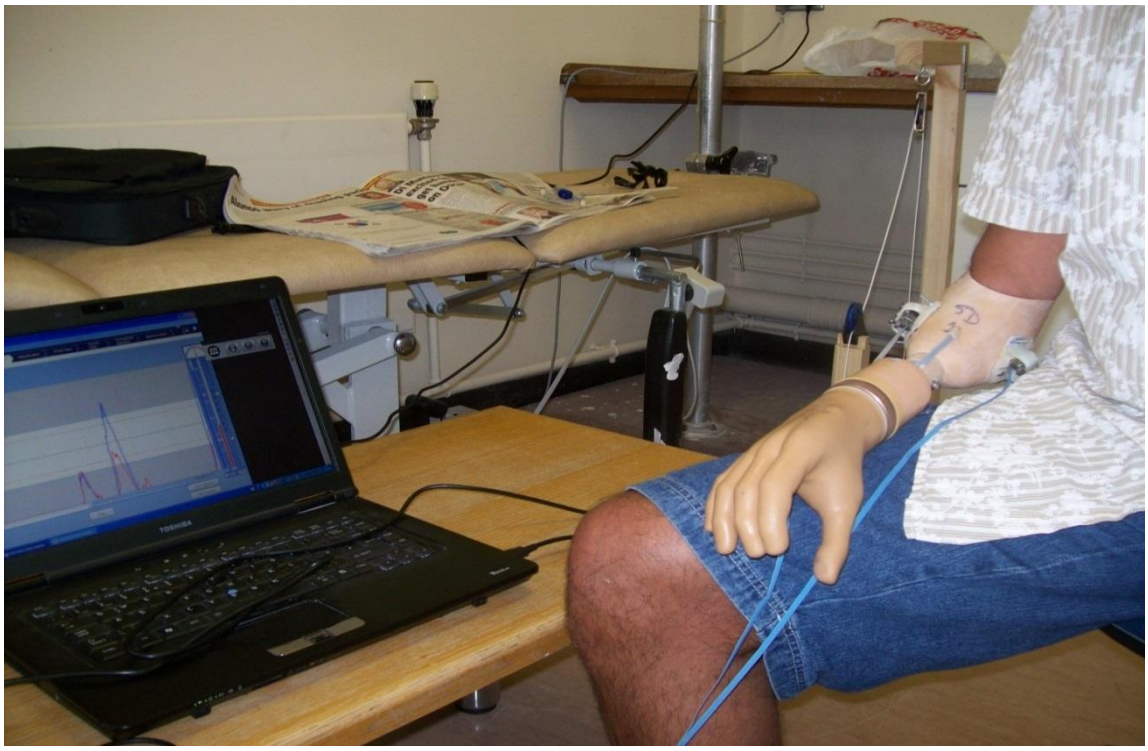

Figure 6.9: Bespoke prosthesis with 'Myoboy' system attached (author's own image).

6.9.1 *Preliminary socket arm motion*

During the preliminary study, it was noted that the author's tissue / skin would be significantly stiffer than that of most residual limbs, given the fact that everyday muscle usage would help to tone the natural forearm. There was little signal acquisition during each of the three motions employed during the preliminary study. However, the positioning of the pulley apparatus was arranged to ensure ease of use and the pulley arrangement was found to be suitable for the purposes of the study.

6.10 *Motion capture*

For an accurate assessment of the effect of each the three motions on the production of motion artefacts within the myoelectric socket, there is a need for an analysis to be made of each motion and at what point, if any, during the motion the artifact is apparent. A number of options were again considered for this study, but an intricate investigation of all the relevant angles that occurred between all of the upper limb joints was not deemed necessary, since the investigation was seeking information regarding the production of motion artifacts from overall movements linked to daily living activities, rather than specific joint positions and motions. For this reason, analytical techniques involving data analysis systems such as the VICON motion analysis system, and other similar motion analysis techniques, were not employed. The chosen option was more simple and straightforward, yet appeared to meet the basic criteria of the study. Each motion was recorded on video camera, along with the corresponding time cycle, which could be coordinated to coincide with the timing of the 'Myoboy' assessment. Consequently, by using frame by frame analysis, any signal activation could be correlated to a specific point during the movement of the arm and the relevant position compared and contrasted with other users during the similar movement cycles.

This technique would therefore be able to determine:

1. Whether any motion artefacts were sporadically generated during any of the motions and load applications on either the 'open' or 'closed' functions of the hand.
2. Whether the production of artifacts were linked to specific movements and therefore certain activities of daily living
3. Whether the addition of loads affected the production of motion artifacts and therefore whether either lifting or moving objects during these movements affected the production of motion artifacts.

4. Whether specific parts during the movement cycle, i.e. movement instigation, movement completion or movement end, were more likely to produce motion artifacts.

6.11 *Subject analysis*

Each subject was provided with a Patient Information Sheet prior to agreeing to be part of the investigation process (see **Appendix B**-*Ethical processes and procedures: patient consent form*). Each aspect of the process was fully explained to the subject before the process was undertaken and the subject was provided with opportunities to ask questions about the nature of the investigation and its implications for both themselves and for the general prosthesis user community.

The subject asked to confirm the comfort level of each socket as satisfactory before any experimental procedure was undertaken. Once this confirmation had been given, and any necessary adjustments had been made, the subject was also asked to conform that the electrode positions were satisfactory and the myoelectric signal strength was tested using a standard myoelectric hand.

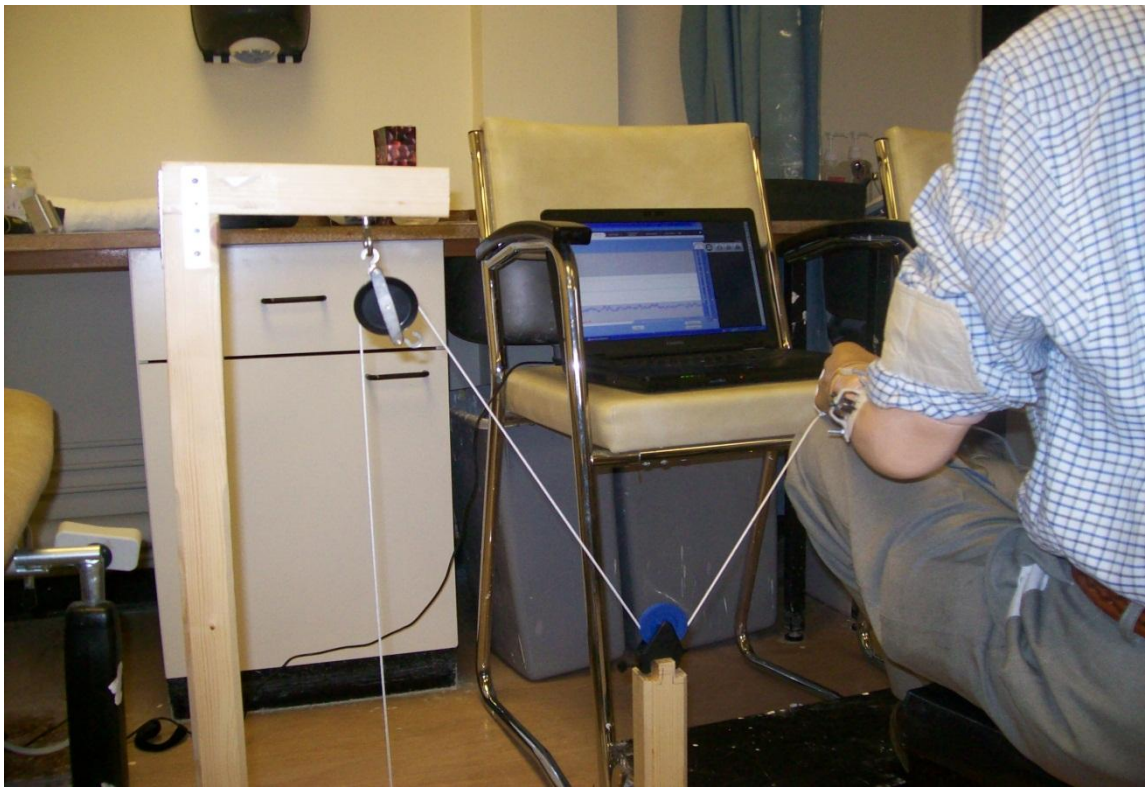

Figure 6.10: An illustration of the seated prosthesis user**,** the movements associated with the motion analysis and the pulley apparatus.

Each subject was supplied with the type of socket most suitable to the length of their residual limb. For subjects with a residual limb length of less than 55% of the natural forearm, a 'Munster' socket or 'Hybrid supracondylar' socket was supplied. For subjects whose residual limb length was greater than 55% of the natural forearm, a 'North-western supracondylar' socket was also supplied. The results from each could then be examined to determine the level of motion that may be expected from the most relevant type of socket under the various conditions that would be reproduced.

The assessment, casting and laminating methods employed for each of the socket types stated previously are illustrated within **Appendix C-** *clinical and technical methodologies***.** The sockets were all laminated using semi-rigid polyester resin combined with 6 layers of nylon stockinet. This mixture created a socket that would accurately replicate the rigidity of sockets usually prescribed within the UK for transradial myoelectric prostheses, an important factor considering the nature of the investigation.

Each socket was fitted independently before it was attached to the endoskeletal prosthesis, to ensure a comfortable fit of a clinically-acceptable standard for myoelectric prostheses. Once this level of fit was established, the prosthesis was then attached, initially set up to match the length of the natural arm from thumb tip to medial epicondyle of the humerus with no external loading attached.

The subject then sat on the chair, and the comfort of the prosthesis, and the seating position, was assured. The assessor then explained the requirements of the three movements (described previously in section 6.3). The subject then practiced each of the movements to ensure that these were fully understood and correct. Once the assessor was satisfied, that the subject understood the movements that were required, the electrodes were fitted within the socket and these were connected to the 'Myoboy' assessment system. The 'Myoboy' system was activated and a new file was created for each user and each movement.

The video was set up to carefully record the movement of the arm (see results section 6.13)**.**

6.12 *Results assimilation*

The 'Myoboy' prosthetic assessment system enables the analyst to determine myoelectric signal generation and acquisition and provides a relative period for the motion for each type of assessment and for each prosthesis user. The data was recorded and saved and the following criteria were identified in accordance with the requirements of the study set out in section 6.6. For each socket, the following data was acquired from the recordings of myoelectric activity produced during each of the movements and under all of the varying conditions of loading:

1. The number of instances where the threshold myoelectric value was reached (this was clearly visible and distinguishable on each recording).
This provided evidence relating the specific movement and / or loading variant with the number of motion artifacts that could potentially interrupt the control of or provide unwanted activation of the myoelectric hand or prehensor.

2. The maximum peak value of any signals produced within the movement cycle (again, this could be clearly distinguished visually).
The maximum peak value showed an indication of the intensity of any signal produced, which would make unwanted activation of the prehensor more likely during this movement.

3. The site of electrode placement producing the artefact during reach motion or movement.
The recorded signals would indicate whether either, or both, of the 'prehensor open' and' prehensor close' electrode sites, positioned on the remains of the wrist extensors and flexors respectively, would be more prone to artefacts during each type of motion.

4. The maximum duration of each signal produced during the respective motion and loading variant.
Longer peak duration would indicate a sustained artifact from a specific motion and loading variant, which again would be more likely to impact on prehensor control and lead to unwanted activation.

Each movement analysis was separated into two key phases:

1. transition-up, representing the movement of the arm from the beginning of the movement sequence up until the end point of the upward motion
2. transition-down, representing the movement of the arm from the end point of the upward motion down to its original starting position

These phases of motion were also used by Kollmittzer et al (2002) who examined the effects of lifting and replacing loads with respect to body movements and posture (266).

The production of myoelectric signals was recorded in each of these phases by analysing and contrasting the video evidence with the recordings made via the 'Myoboy' assessment system. Distinct electrical signals, representing the production of motion artifacts, could also be related to relevant parts of the movement cycle. For example, any interruptions in the smooth transition of the movement or any clear deviations from the accepted movement path during the motion could be noted and related to the relevant responses and recordings taken using the 'Myoboy' system.

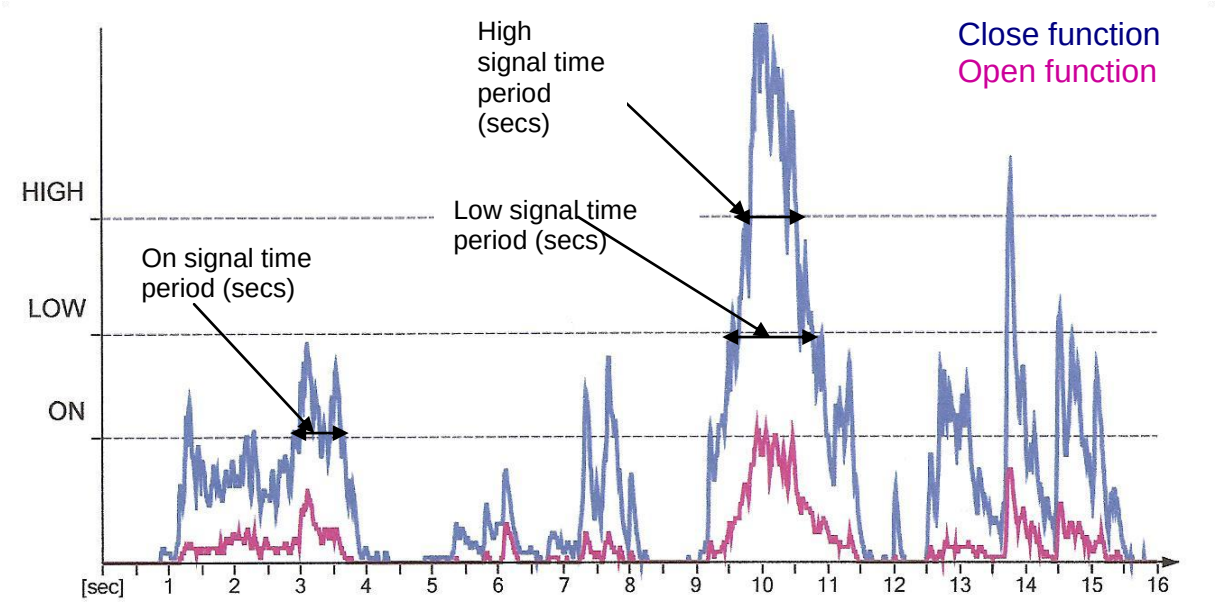

Fig 6.11: Myoelectric signal illustration received from the 'Myoboy' assessment.

The motion artifacts generated during each of the daily activity simulations only become significant once they pass the 'on' or hand activation threshold of the myoelectric

control system (see **figure 6.11**, above). On a standard threshold-controlled hand, the duration of this signal will then determine the activation duration of the hand i.e. the hand will open or close at its fixed speed for as long as the signal remains above the threshold. If the signals are very short, then the hand may not have time to react or it will simply vibrate briefly in response to the signal. This is a common reaction when users are learning to use the myoelectric control system and are learning to produce signals of suitable size and strength.

In terms of its capability to interrupt or inhibit control, the motion artifact has two key components: size and duration. These factors will therefore need to be considered in any illustration of overall motion artifact production with respect to the movements previously described.

The normal variation in myoelectric signal production and its subsequent appearance (see **figure 6.11**) makes systematic analysis of these signals inherently challenging. Simply producing one signal for one movement, and offering this as a defining illustration, is clearly flawed, but composing an average is also unviable, as the signals appear as graphical representations rather than numerical values. However, these graphical representations do offer information showing signal duration and strength at specific times during the signal (**figure 6.11**) and are easier to visualize and contrast with normal myoelectric contractions than numerical values.

It was therefore decided to determine a ‘typical’ myoelectric signal pattern using signals generated from at least 10 repetitions of each movement, using signal strength and duration as the defining elements in the overall shape of the signal. The typical signal strength could be identified as the ‘mode’ signal pattern that was developed during the repeat movements.

The subject was asked to perform each movement at approximately the same velocity. This velocity could be identified as reasonably natural, and repeatable, and wouldn’t risk either residual limb discomfort during the movement or significant variations in the movement trajectory. The velocity selected was 3-4 seconds from the prosthesis starting and ending each respective movement in the same position.

The points during each movement where the signal rose above the 'on' or threshold level, the low signal level and the high signal level, and the duration of the signals above these thresholds at these points, were determined using the 'Myoboy' analysis. Each signal pattern was saved and the duration contrasted with the video recording in order to ascertain the positions of the peaks in reference to the movement trajectory (see **fig. 6.12** below).

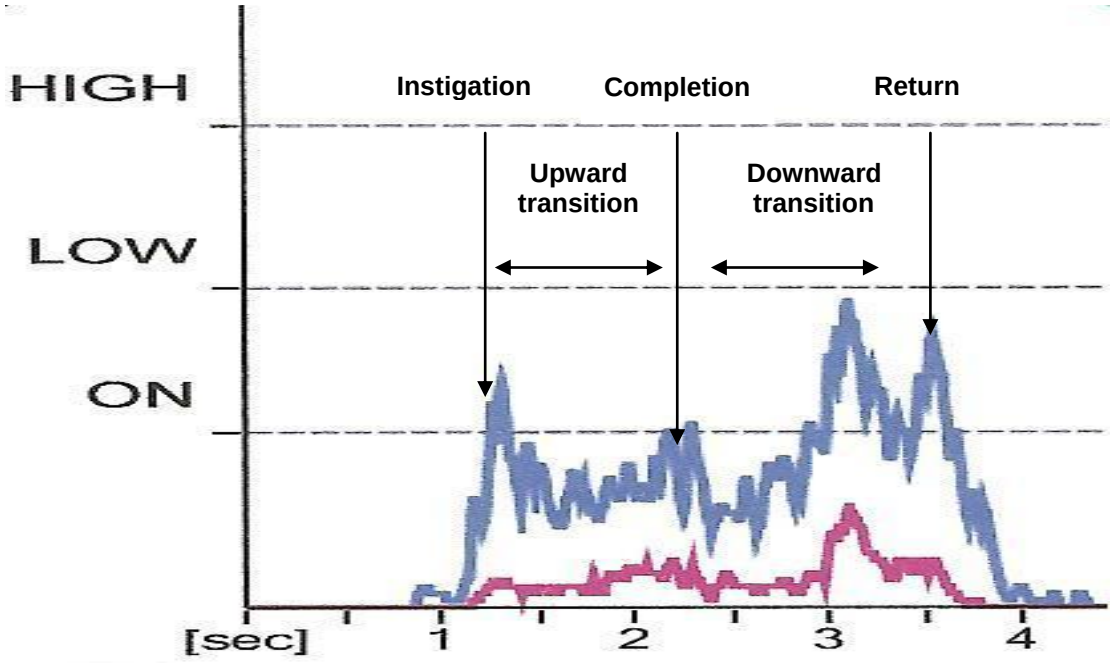

Figure 6.12: Myoelectric signal represented graphically, showing key points within the movement activity.

In addition to recording the motion artefacts in terms of their strength and duration, it was also important to record at what points during the movement where they were generated, or at least appeared to be more likely to occur. This is where the video analysis was able to assist in the process. The video analysis was able to confirm that each movement cycle conducted by each subject was approximately 3-4 seconds in duration, split almost always equally between the upward and downward transitions.

The video analysis also highlighted the above zones as representative of the times when each phase of motion would take place. This meant that the production of the motion artifacts could be linked to particular areas of the activity which would be most likely to induce a false signal from the hand.

Figure 6.11 demonstrates the zones of activity that each movement would produce:

1-Movement **instigation**-initial motion from the starting position **(figure 6.1);**

2-Movement **completion**-the end point for each motion **(figures 6.2-6.4);**

3-Movement **return**-the end of the motion sequence **(figure 6.1).**

The signal pattern could not easily be transferred from the 'Myoboy' software; each patterns had to be printed, then subsequently scanned and saved, onto a suitable computer. The patterns for each movement, under each condition, from each subject, are represented in the following section.

6.12.1 *Comparing the motion artifact signal with one created by muscular contraction*

The appearance of a 'normal' myoelectric signal, as it appears on the 'Myoboy' assessment system, should be recognised and noted, since this will provide a visual comparison with other signals, or motion artifacts, which may be produced. Therefore, each subject was asked to perform the 'open' and 'closing' functions whilst on-line with the Myoboy system. A typical myoelectric signal, as produced voluntarily by each user, is illustrated below in **figures 6.13 & 6.14**:

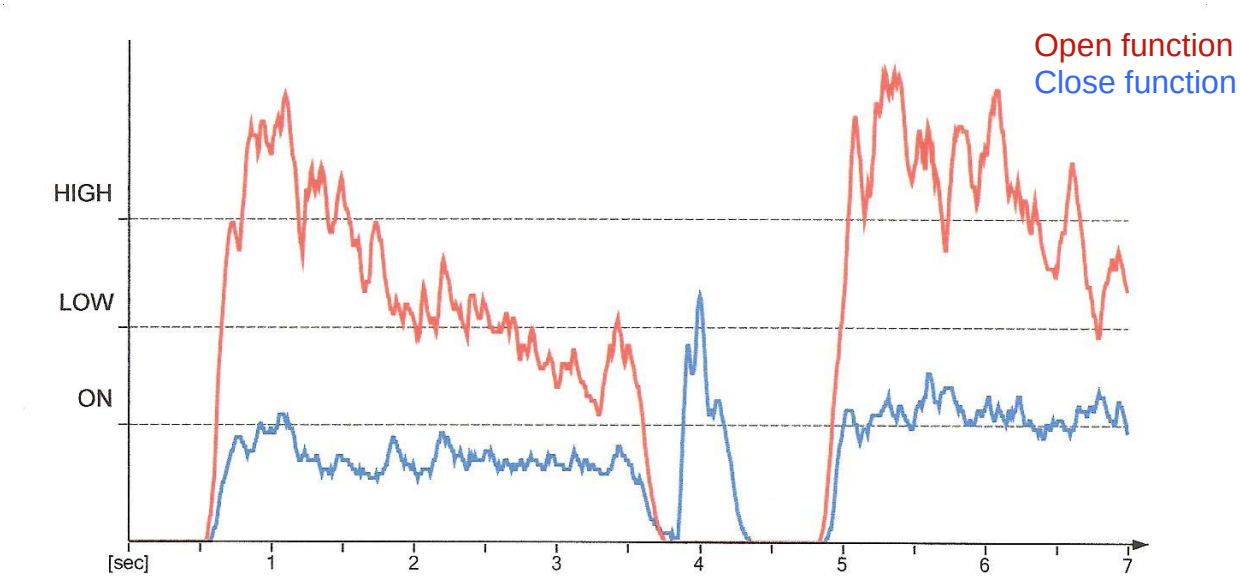

Figure 6.13: Typical myoelectric signal, produced by subject 'C', for the 'open' function

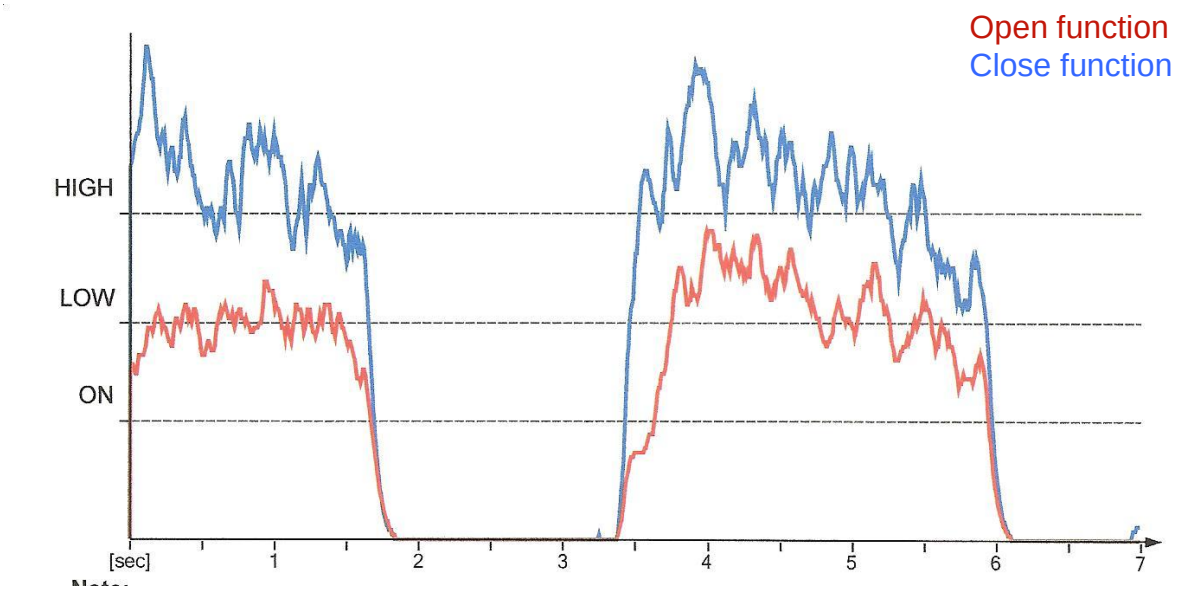

Figure 6.14: Typical myoelectric signal, produced by subject 'C', for the 'close' function

For the purpose of effective analysis, typical examples of each movement will be selected for discussion.

6.12.2 *Subject identification*

There were 5 subjects used in the study; 8 subjects were originally invited to participate, 2 were unable to participate for personal reasons and one user failed to attend on the specified appointment dates.

The subjects used in the study are identified in the following table:

Subject	**Cause of limb absence**	**Type of Socket fitted**	**Limb length (short/medium/ long*)**	**Myoelectric control used / experienced**
A	Trauma	North-western	Long	Threshold
B	Congenital	Munster	Short	Threshold
C	Congenital	Hybrid	Medium	Threshold
D	Congenital	Hybrid	Short	Threshold
E	Trauma	Hybrid	Medium	Threshold

See limb length classification,* ***chapter 2*

Table 6.2: Subject identification and data sets

With regard to the cause of limb absence, the subjects in **table 4.1** correlate well by proportion with those prosthesis users responding to the questionnaires in **chapter 3.**

Limb length is also noted, since the effective lever arm that the residual limb is able to provide during the movements could potentially influence the activities that are performed; particularly the 'reach' activity where the arm will be held extended and lifted in front of the subject.

The socket type used for each subject is also potentially significant. Each socket type employs different anatomical structures to suspend and secure the prosthesis; these variations may be significant when certain activities are performed. For example, the 'Munster' socket employs an 'anterior-posterior' type of suspension with respect to the residual limb, whereas the other, 'supracondylar' socket types employ a 'medial-lateral' type of suspension. For the 'hand to shoulder' movement, the differences in the anterior trim lines of each socket type may affect the user's movements and the subsequent effect on the sockets position with respect to the residual limb during the movement.

The sockets were fitted accordingly with regard to both:

- Previous prescription
- Length of residual limb

The variance between the lengths of the residual limbs and the socket types could also potentially influence the production of motion artefacts, since the sockets prescribed at these levels employ different anatomical reference points for suspension.

6.13 *Movement analysis and discussion*

Motion artifacts were commonly distinguished during all of the activities performed by the subjects, to varying degrees, dependent upon both the type of activity being performed and the loads applied during the movement. Signal patterns for subject 'C' will primarily be used to illustrate the effects of different movements and the application of loads within this section. However, a complete list for all subjects is available within **Appendix D-** *results of motion artifacts and movement analysis*.

6.13.1 *Motion artifact signal patterns for each activity*

The results indicated that distinct, reproducible motion artifact patterns were produced during two of the three motions, the 'reach' activity set, and the 'hand to shoulder' activity set. The 'hand to hip pocket' activity set reproduced a more variable response in terms of signal production. There was however a distinct variation in the number, intensity and duration of these motion artifact signals depending on the activity undertaken and the amount of load applied. The following figures show the responses provided by subject 'C'. The remaining plots for the other four subjects (A, B, D, E) are provided within **Appendix D-** *results of motion artifacts and movement analysis*.

6.13.2 *Movement analysis: 'Reach' activity*

6.13.2.1 *No load*

Each subject was able to perform the 'reach' activity relatively easily without the addition of extra load. The typical signal response recorded during these movements is illustrated in **figure 6.15:**

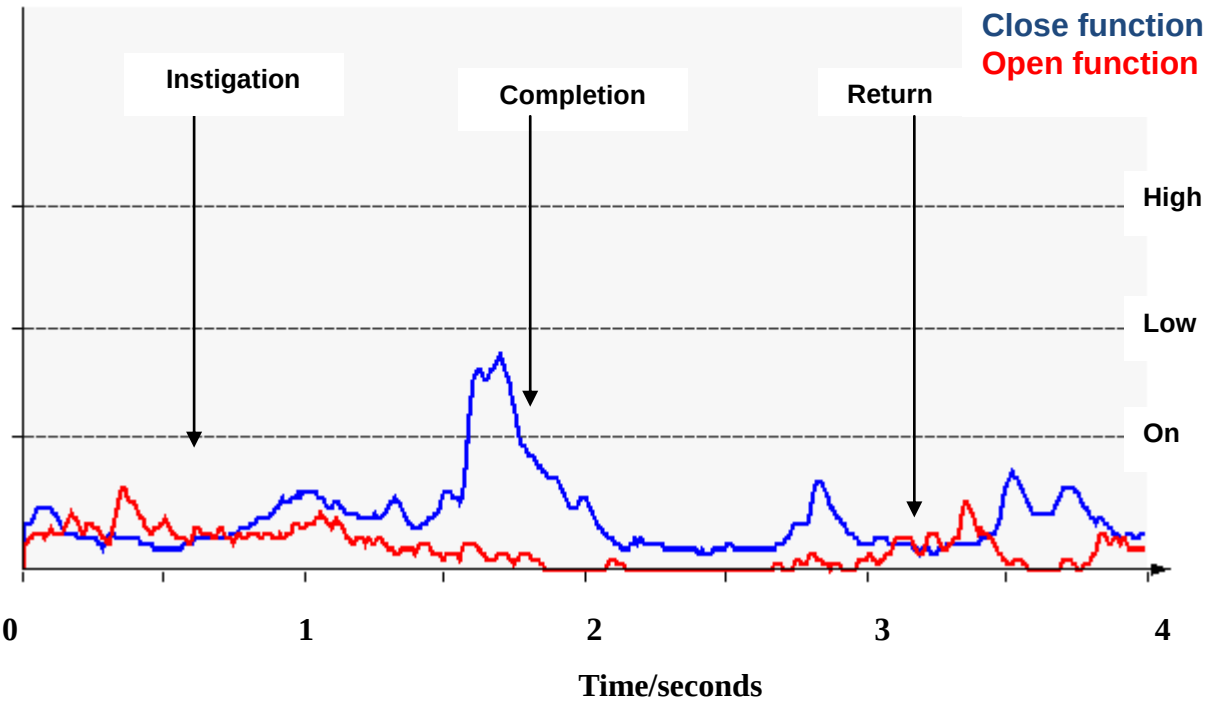

Figure 6.15: 'Reach' movement performed under no load by subject 'C'.

Although performing these movement, and therefore activities, produced some signal responses, there were usually below the threshold of response, even at relatively high amplification (gain) settings.

Additionally, the signal patterns were relatively uniform and continuous, with signal peaks rarely above the threshold (ON) level for most subjects. The most likely period during the movements when a post-threshold signal could occur was on the **completion** of the movement, at the end of the upward transition period (see **figure 6.15**). Other than this, there was little apparent variation in the signal pattern during each movement cycle.

In all but one of the subjects, the function most likely to be affected during the reach activity with no load was the 'close' function. However, for subject 'A', the 'open' function was most obviously affected (see **Appendix D-** *results of motion artifacts and movement analysis*).

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6.13.2.2 ***Addition of loads***

The 'reach' activity produced more motion artifacts upon the addition of loads, most clearly when the larger 1Kg load was added. Upon the addition of 500g, the typical signal pattern displayed by subject 'C' during the movement is illustrated in **figure 6.16** below:

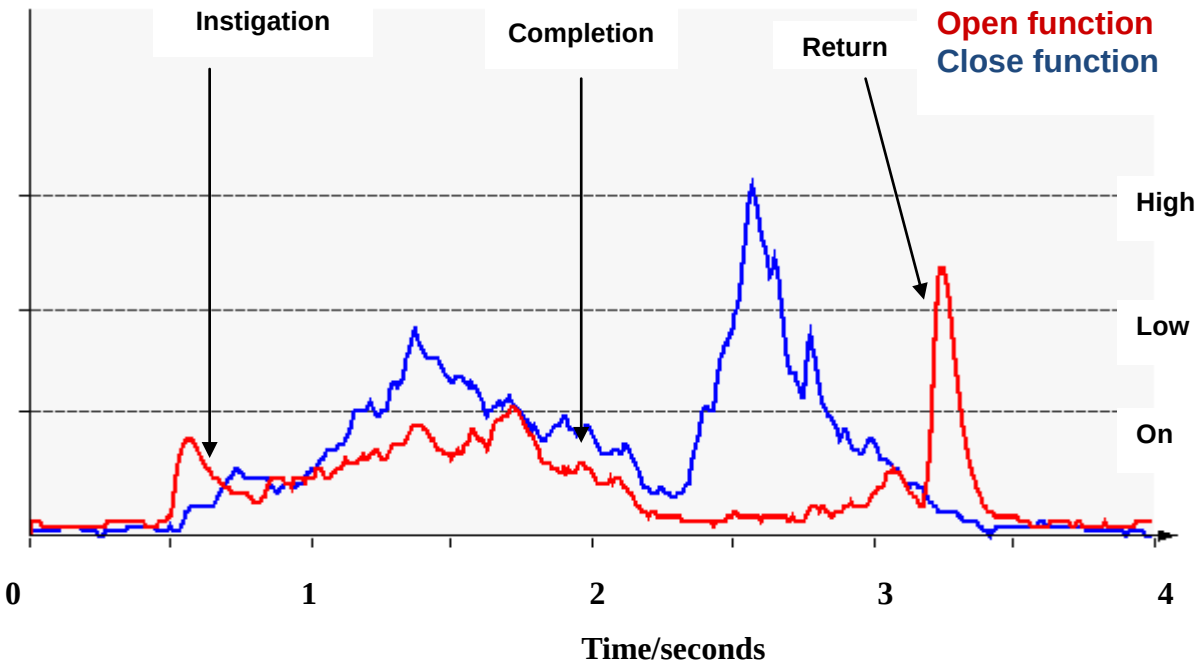


Figure 6.16: 'Reach' movement performed with 500g load by subject 'C'.

In some subjects, a small signal on the 'open' function occurred during movement instigation, as the prosthesis was initially raised from the subject's thigh, or at the completion of the movement. However, both of these were relatively small; the main signal produced was for the 'close' function except for subject 'A'. The addition of an even larger 1Kg load produced a much larger signal pattern, with a continuous number of peaks well above the signal threshold, for all users except subject 'A' on the 'close' function, mimicking the 'normal' myoelectric signal (**figure 6.17**):

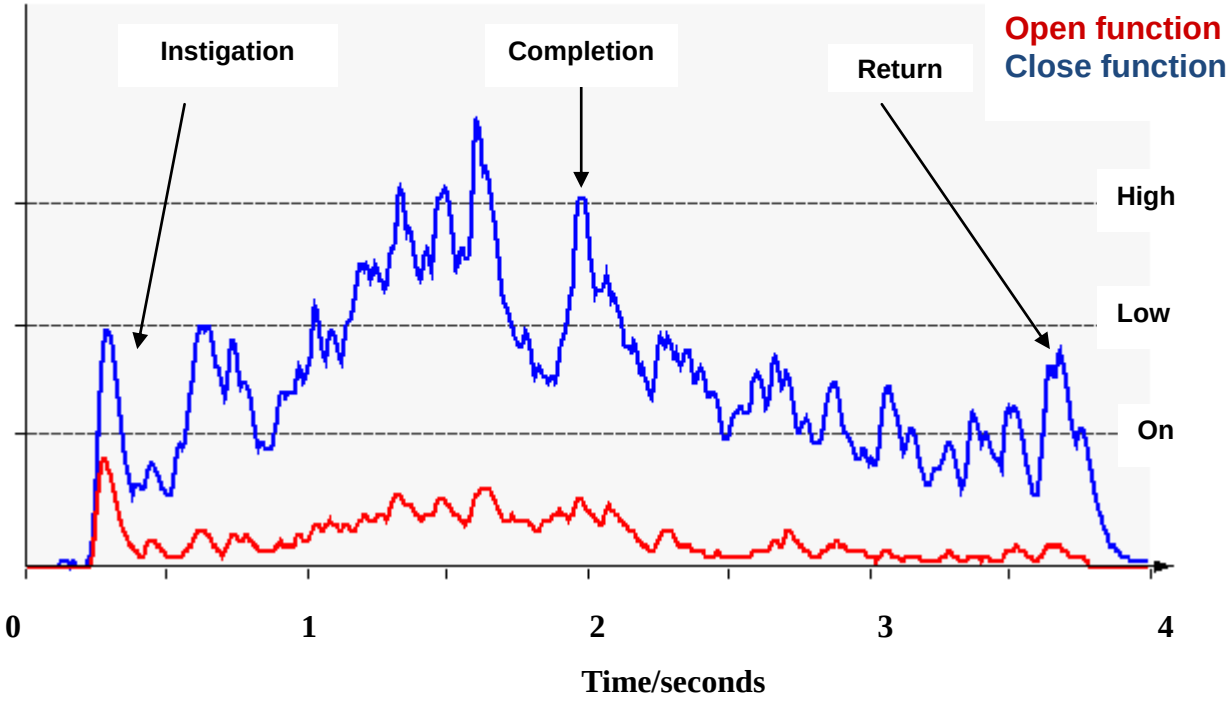


Figure 6.17: 'Reach' movement performed with 1Kg load by subject 'C'.

The upward transition of the movement cycle was particularly prone to signal production, and the pattern depicted a relatively proportional signal size to the amount of movement undertaken, with the upward transition of the movement cycle producing relatively larger signals in most cases.

6.12.2.3 *Assessing and analysing the addition of loads*

The 'reach' activity produced a motion artifact signal pattern that most closely resembled the myoelectric signal produced from a contracting muscle (see **figures 6.12** & **6.13**). The signal produced during the 'reach' activity generally tended to plateau, at low loads up to 500g, indicating that the motion artefacts produced did not increase as greatly in size during the duration of the movement. When performed in tandem with the 1Kg load, the

movement produced signals with defined largest peak signal strengths around the completion point of the movement, i.e. when the prosthesis was fully extended in front of the subject.

Tables 6.3 and **6.4**, and **figure 6.18** (below) illustrate the effects of the addition of loads following a manual numerical assessment and measurement of the graphs as shown for the 'reach' activity for subject 'C':

Load	**Total time for activity / secs.**	**Time above 'ON' threshold / secs.**	**Time above 'LOW' threshold / secs.**	**Time above 'HIGH' threshold/ secs.**
0Kg	2.8	0.2	0	0
500g	2.9	1.0	0.2	0
1Kg	3.0	2.4	1.0	0.3

Table 6.3: Time of signal duration relative to each signal threshold ('reach')

Signal threshold	**1 Kg**	**500g**	**No load**
On	80%	33%	10%
Low	34%	7%	0
High	7%	0	0

Table 6.4: Proportion by % of signal above each threshold from instigation to return ('reach')

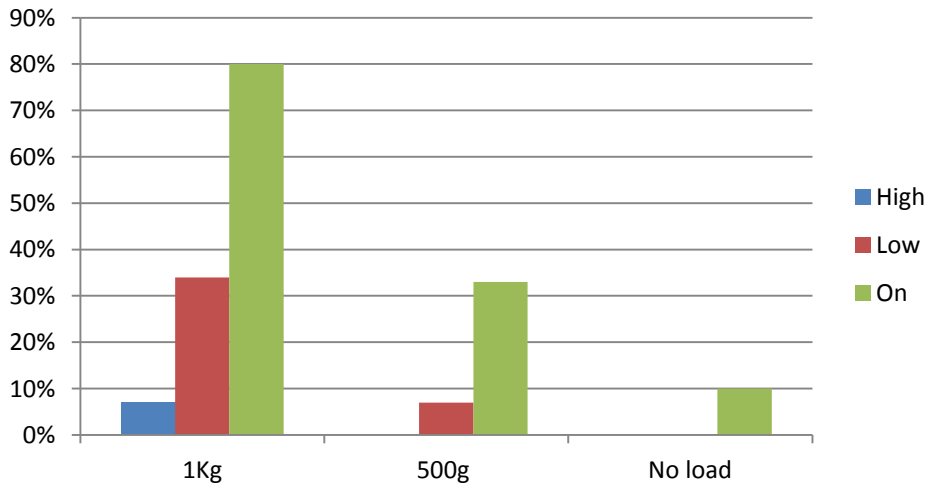


Figure 6.18: Proportion by % of signal above each threshold from instigation to return ('reach')

The proportion of signal duration above each threshold under each load, as illustrated above (**figure 6.18**), shows a linear trend, indicating that the addition of load has a relatively proportional effect on signal increase and duration. Under no additional load, the signals normally appeared to be too small and sporadic to affect hand control to any large degree. Increasing the load on the prosthesis during the 'reach' activity did produce larger, longer signals, particularly under the largest 1Kg load. This could have been due to the effect of the extended lever arm that was maximized when the prosthesis was held out straight in front of the subject. This may account for the significant increase in the size of the motion artifact generated at the completion point under the effect of the additional 1Kg load in particular.

This analysis suggests that activities involving smaller loads, such as pointing to an object, would potentially be less susceptible to motion artifact production than activities involving heavier loads, such as lifting an object and placing it on a shelf. Another factor to consider however would be the weight of the myoelectric hand and other components within the prosthesis, particularly those at the distal end of the prosthesis. Incorporating heavy prosthesis components could produce larger motion artifacts during reaching activities without any additional load being lifted or carried.

6.13.3 *Movement analysis: 'Hand to shoulder' activity*

6.13.3.1 *No load*

Signals produced from the 'hand to shoulder' activity generally produced higher peak signals than those from the reach activity at no load. The pattern was also more distinctive, with a far more pronounced peak at the movement completion phase of the activity (see **figure 6.19**, below :

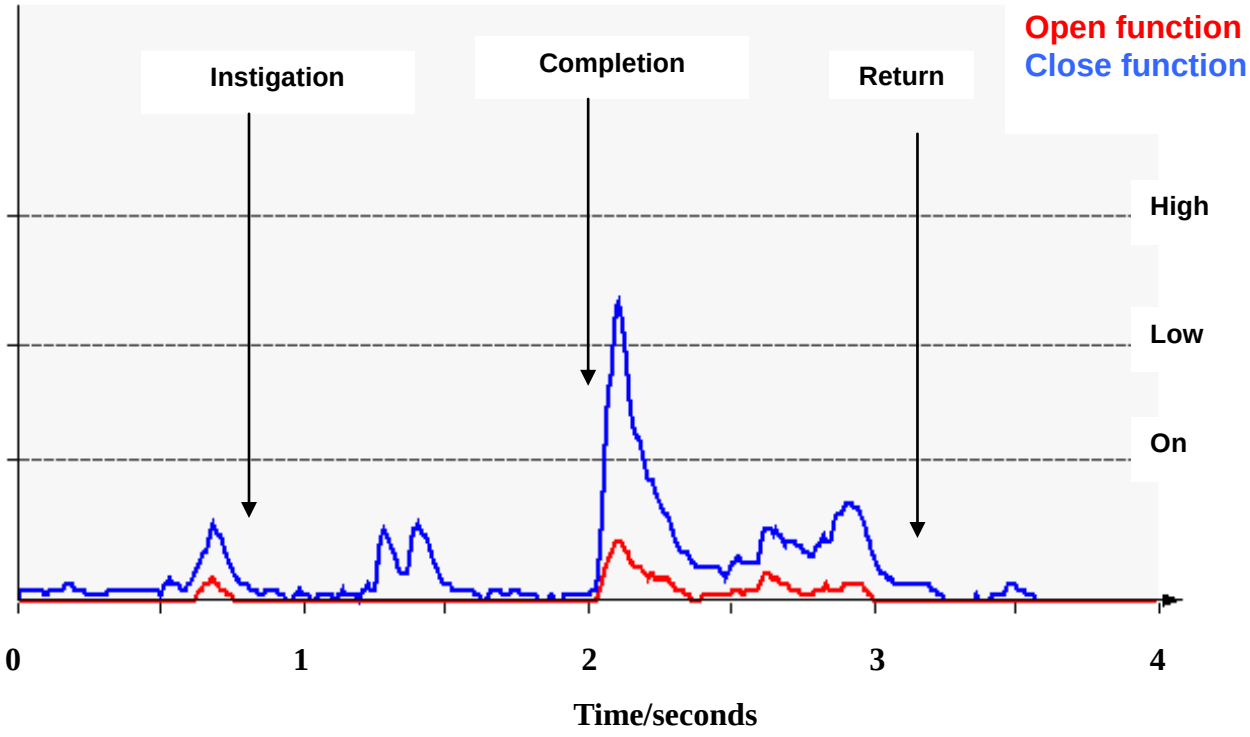


Figure 6.19: 'Hand to shoulder' movement performed under no load by subject 'C'.

6.13.3.2 *Addition of loads*

The addition of loads produced the signal patterns for subject 'C' as shown in figures 6.20 & 6.21.

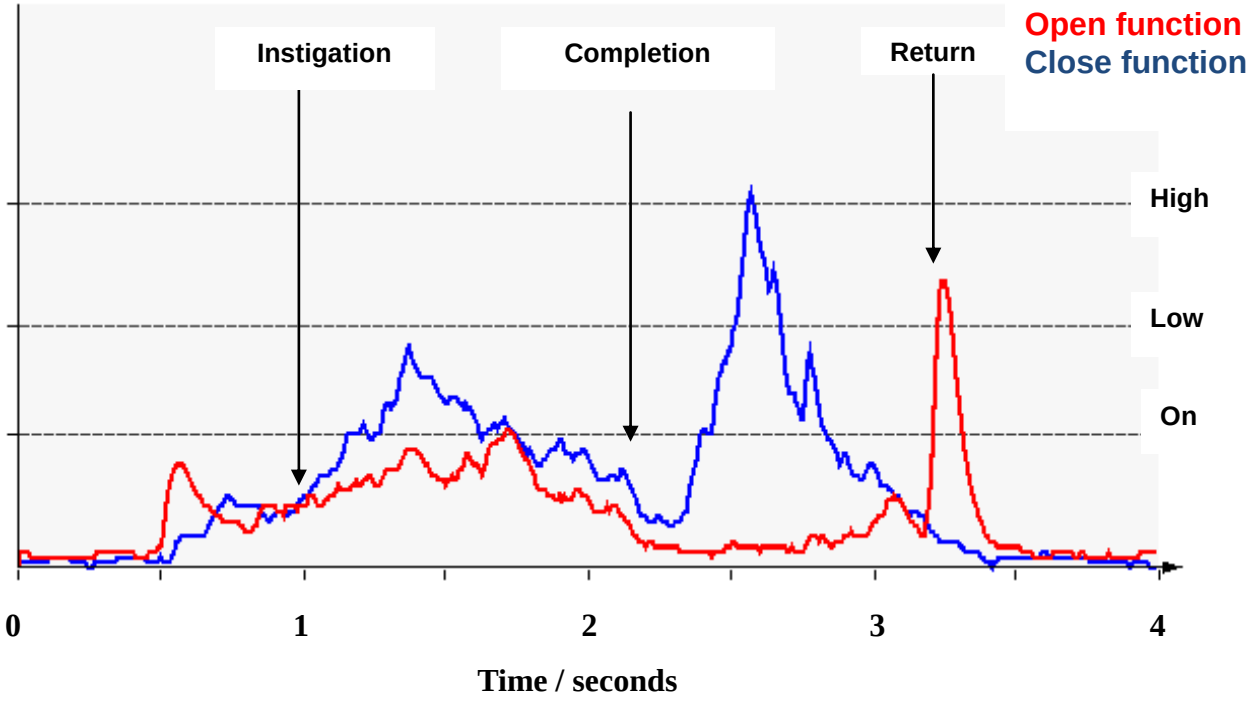


Figure 6.20: 'Hand to shoulder' movement performed with 500g load by subject 'C'.

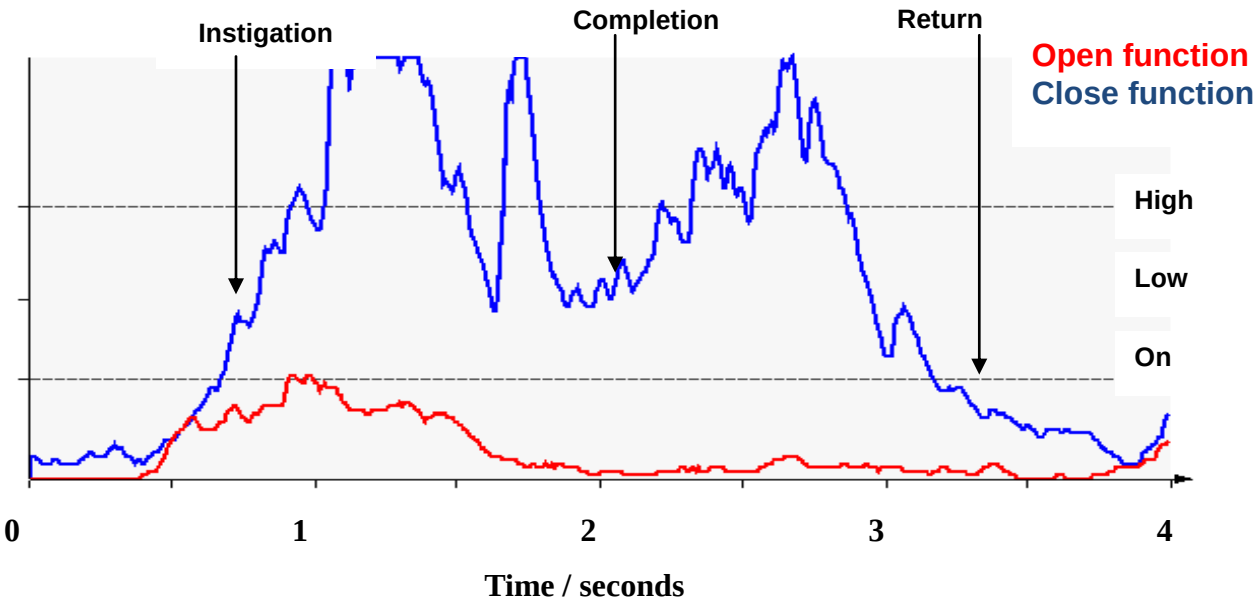


Figure 6.21: 'Hand to shoulder' movement performed with 1Kg load by subject 'C'

6.12.3.3 *Assessing and analysing the addition of loads*

Tables 6.5 & 6.6 and **figure 6.22** (below) illustrate the effects of the addition of loads following a manual numerical assessment and measurement of the graphs as shown for the 'hand to shoulder' activity for subject 'C':

Load	Total time for activity / secs.	Time above 'ON' threshold / secs.	Time above 'LOW' threshold / secs.	Time above 'HIGH' threshold/ secs.
0Kg	3.5	0.2	0.1	0.0
500g	2.2	1.7	0.7	0.2
1Kg	3.0	2.8	2.3	1.3

Table 6.5: Time of signal duration relative to each signal threshold ('hand to shoulder')

Signal threshold	1 Kg	500g	No load
On	93%	77%	43%
Low	77%	32%	9%
High	18%	12%	6%

Table 6.6: Proportion by % of signal above each threshold from instigation to return ('hand to shoulder')

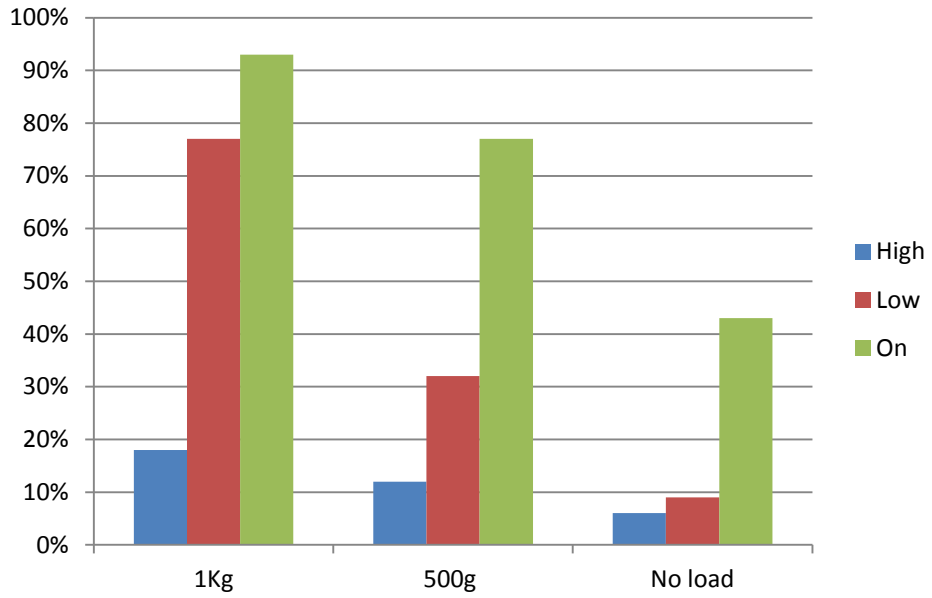


Figure 6.22: Proportion by % of signal above each threshold from instigation to return ('hand to shoulder')

The movement completion phase was again most likely to produce a signal; in most cases, the signals were well over the threshold required to potentially initiate the hand response.

The 'hand to shoulder' movement tended to produce motion artifacts with a more distinct signal peak at the completion point of the movement, when the prosthesis was effectively placed on the subject's sound side shoulder. These signal patterns were evident even at no load, or 500g loads, and were potentially strong enough to affect prehensor activation particularly at the completion point.

The 'hand to shoulder' movement would replicate activities involving the hand being placed near the mouth (e.g. for eating) and therefore would potentially influence the ability of the subject to release food within the hand (for subjects 'B', 'C', 'D', 'E') or to successfully pick up and retain the food within the hand (subject 'A').

6.13.4 *Movement analysis: 'Hand to hip pocket' activity*

6.13.4.1 *No load*

The 'hand to hip pocket' activity produced more erratic signals than either the 'reach' or the 'hand to shoulder' activities. However, there was still some correlation between the size of the signals produced and the size of the load used in each movement activity.

For no load, often smaller, erratic peaks were produced, in a generally similar format to that shown in **figure 6.24** (below):

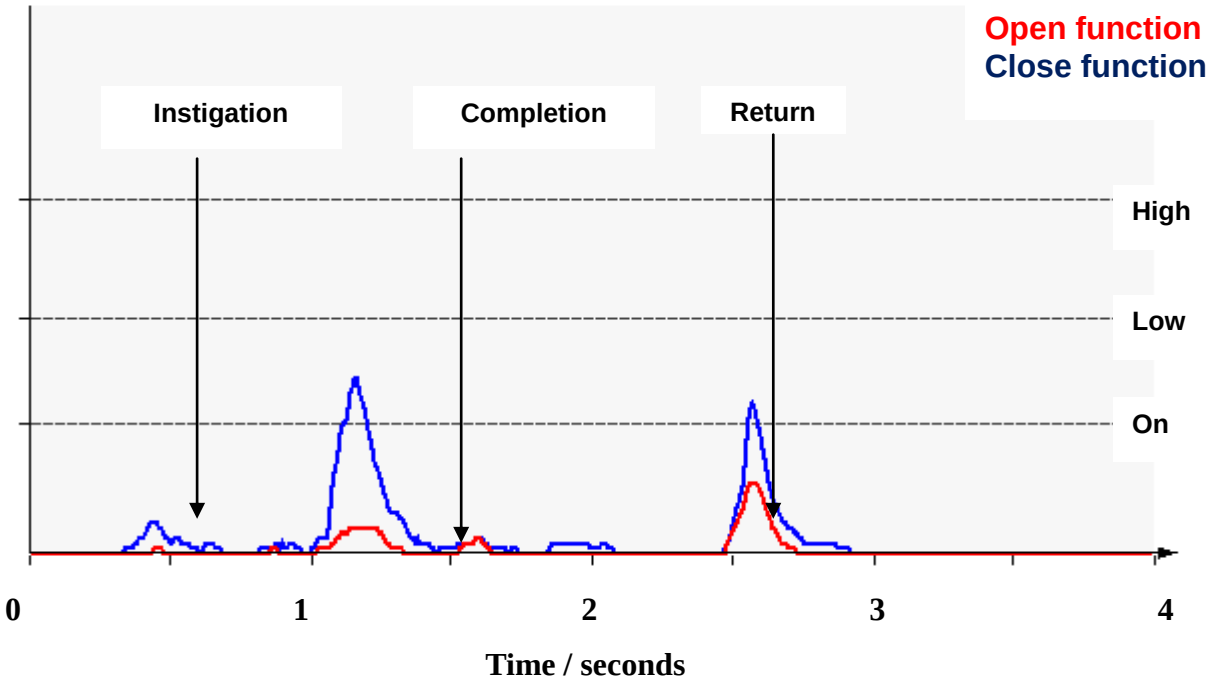


Figure 6.23: Hand to hip pocket movement performed with no load by subject 'C'

6.13.4.2 *Addition of loads*

With the addition of loads, the signals became even more erratic. The addition of loads for this movement activity produced similar signal patterns as shown below in **figures 6.23** and **6.24** for subject 'C':

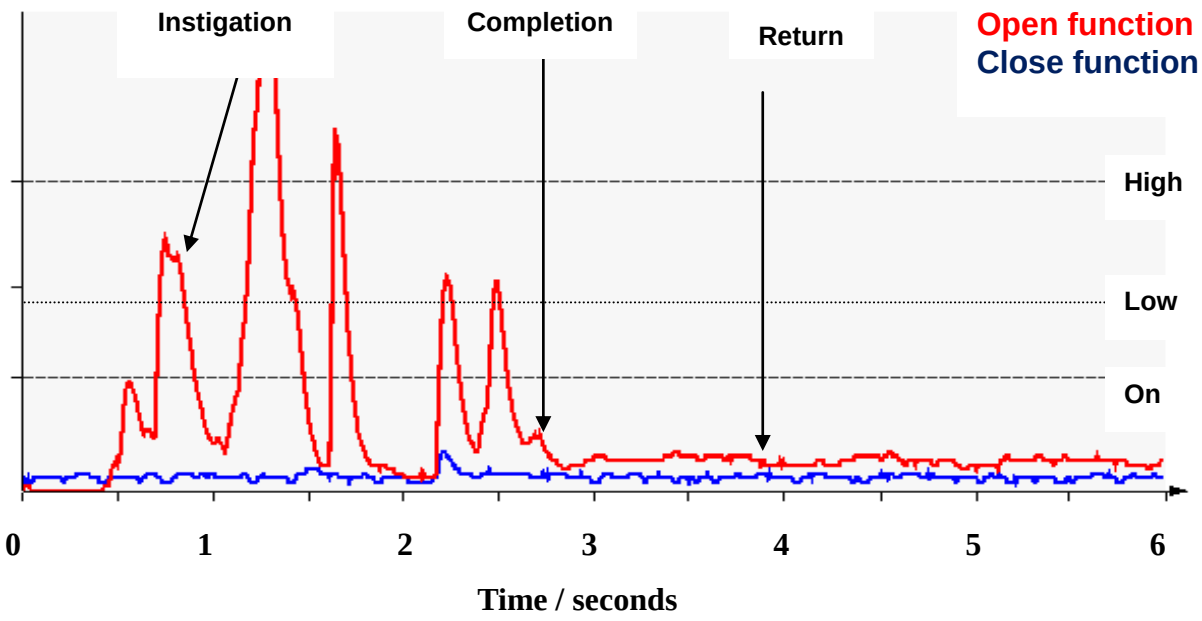


Figure 6.24: Hand to hip pocket movement performed with 500g load by subject 'C'

This activity produced the most erratic signal patterns. In many cases, unlike the other two activities, there appeared to be no distinct correlation between the completion point and the largest evident signal, or even the affected site ('open' or 'close'). This activity was noted by each subject as the most difficult to complete; this may explain the erratic nature of the recorded signals, since the subjects were often straining to make the prosthesis index finger reach their hip pocket.

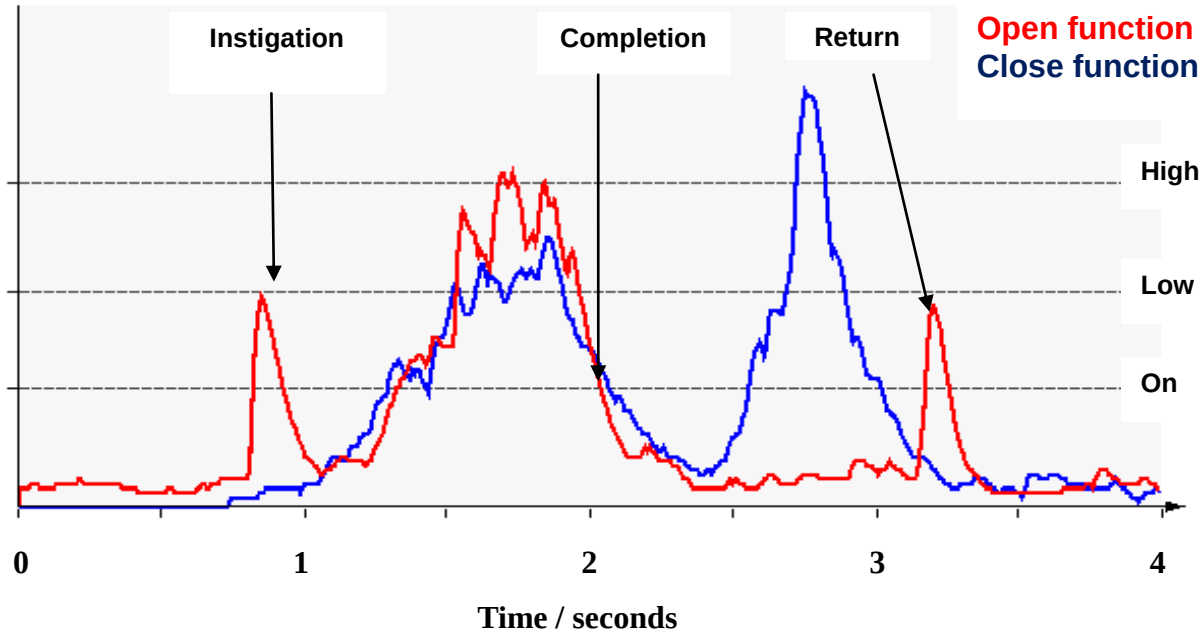


Figure 6.25: Hand to hip pocket movement performed with 1Kg load by subject 'C'

Most post-threshold signal peaks were recorded during the hand to hip pocket movement under the 1Kg load, during the 'transition up' phase of the movement. All five subjects recorded more than 4 separate post-threshold signals which were theoretically large enough to create motion artifacts and unwanted activation of the hand or prehensor during this motion and with this particular loading variant.

6.12.4.3 *Assessing and analysing the addition of loads*

Tables 6.7 & 6.8 and **figure 6.26** (below) illustrate the effects of the addition of loads following a manual numerical assessment and measurement of the graphs as shown for the 'hand to hip pocket' activity for subject 'C':

Load	Total time for activity / secs.	Time above 'ON' threshold / secs.	Time above 'LOW' threshold / secs.	Time above 'HIGH' threshold/ secs.
0Kg	3.5	0.2	0.0	0.0
500g	3.2	1.0	0.6	0.2
1Kg	2.9	1.9	0.7	0.1

Table 6.7: Actual time of signal duration relative to each appropriate signal threshold ('hand to hip pocket')

Signal threshold	1Kg	500g	No load
On	66%	21%	6%
Low	24%	19%	0%
High	3%	6%	0%

Table 6.8: Proportion by % of signal above each threshold from instigation to return ('hand to hip pocket')

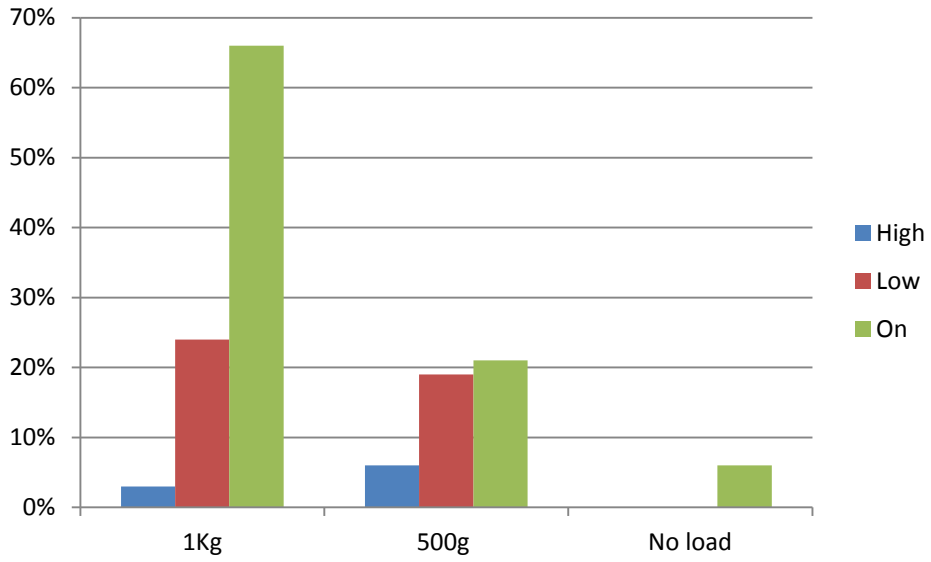


Figure 6.26: Proportion by % of signal above each threshold from instigation to return ('hand to hip pocket')

6.13.5 *Affected electrode sites and respective activation functions*

For virtually all the 'reach' and 'hand to shoulder' movements, for all the subjects, one electrode site was affected by motion artefacts more distinctly than the other site, although this was not as clearly defined with the 'hand to hip pocket' activity. For subjects 'B', 'C', 'D' and 'E' this unwanted activation would invariably affect the 'close' function of the myoelectric hand. For these subjects undertaking the 'reach' activity with their prosthesis, to place an object on a shelf, for example, there would be a tendency for the object to be difficult to release at full extension, as unwanted activation of the 'close' function would disrupt these subject's attempts to open the myoelectric hand. For the 'hand to shoulder' movement, the peak was usually more defined at the completion point of the activity.

For subject 'A', the motion artifact appeared to affect the 'open' function, meaning that any object lifted and moved in a similar manner by this prosthesis user could be dropped as the arm extended into the 'reach' position.

For all subjects, employing the 'reach' activity would therefore potentially be problematic. Subject 'A' stated that he had "noticed that his hand would open inadvertently during the 'reach' movement", and was able to demonstrate this using his own prosthesis.

Subject ‘A’ had the longest residual limb of all those subjects used in this study, over 55% of the sound side equivalent forearm length and consequently was fitted with the only ‘North-western supracondylar’ socket used. In addition, subject ‘A’ had electrodes sited more distally within his socket than the corresponding electrodes within the other subjects’ sockets. The electrode sites in subject ‘A’’s prosthesis did not sit over the remains of the largest muscle bellies, but were sited where the largest, most distinct myoelectric signals were available. These sites also corresponded to the sites used within the subject’s own myoelectric prosthesis

The affected sites were much more variable for the ‘hand to hip pocket’ activity, with both electrode sites being affected for most of the subjects sporadically throughout this movement.

6.14 *Limitations and potential errors*

There were a number of factors that should be considered with regard to the results obtained from this investigation. Firstly, the respective starting points between the basic video analysis and the results data from the ‘Myoboy’ could only be estimated, and were not directly calibrated. Therefore estimations of exactly when the larger signal artifacts were produced were just that-estimates. Analysis of the data sets of each of the movements and associated artifacts was subjective, and depended on the assessment of the shapes produced, in order to form an ‘average’ for each artifact graph shape under each assessment condition.

In addition, the exact movements were not related to specific joint angles, but rather to daily living activities that encompassed numerous joint positions, which may be accomplished slightly differently between subjects. Nevertheless, the objective of the analysis was not to find direct links with joint angles, but moreover, to suggest if actual activities, which could be used in training regimes, were more likely to produce artifacts and specific responses. Therefore, the results were deemed useful, since it was the activities, not the actual segmental analysis, that was most useful in order to meet the requirements of this thesis.

6.15 *Chapter summary*

The movements used in this investigation were simple to reproduce, but are commonly practiced during daily living activities. The results show that post-threshold signals are rarely produced during these movements when the electrodes are adhered to the

forearm in similar positions to those used in prosthesis control. This suggests that any motion artefacts produced from the prosthesis user subjects during the assessment were as a result of movement between the socket and the skin, rather than any other cause, e.g. inadvertent firing of the target muscles during the movements. Myoelectric signals normally produced from the natural forearm are inherently stronger than those that would normally be produced from muscles remaining within the residual limb. Therefore, it is reasonable to deduce that any inadvertent muscle activity caused by the movements during the prosthesis assessment would also be insignificant.

Prosthesis users undertaking certain daily living activities, corresponding to those shown within this study, can potentially induce motion artifacts large enough to interfere with myoelectric control. This of course will also be linked to the amplification at each of the signal sites; if this is reduced, then the size of the motion artifacts should also be reduced. However, this may then preclude direct control of the myoelectric hand. All the subjects within this study employed amplification levels which had been tested prior to the commencement of the study as being the minimum required to obtain appropriate levels of myoelectric control. Any subsequent reduction in the signal amplification may therefore reduce the subject's ability to open and close the myoelectric hand.

For effective prosthesis control, the subject should be able to instigate movements and subsequent prehension without inducing motion artefacts. Prosthesis training may be improved if further studies are undertaken which can further specify which activities should be avoided by subjects who employ specific types of sockets, and which movements can more safely be used instead to compete daily living tasks. By educating the prosthesis user, it may be possible to engage the use of more daily living tasks, which in turn may provide more long terms functional benefits for those using myoelectric prostheses.

Although effects on the 'close' function may appear to be less problematic than the 'open' function in some cases, such as pointing, the reality is that any affected site could potentially influence the capability of the prosthesis user to undertake a specific daily living activity. Most activities will require effective control of both sites at all times; if false signals are being created, then these will naturally interfere with the completion of any given task, regardless of which site is mainly affected.

Although there were variations between subjects in terms of signal size and duration, the shapes of the signal graphs were similar for most subjects for each of the movements, indicating a recognizable link between socket movement and motion artifact production. This could help to determine potential problems in specific daily living activities for myoelectric prosthesis users. Specific activity-based pre-prosthesis and post-prosthesis training could be provided, educating users with regard to specific actions that should be avoided and highlighting actions and activities that can be performed without myoelectric hand disruption.

Chapter 7: Conclusions and future research

7.1 *Conclusions*

The overall hypothesis of this thesis (stated within **chapter 1)** was that myoelectric prosthesis control is adversely affected by relative movements between currently employed socket designs plus their electrode housings, and the residual limb within the socket. The results from the chapters and investigations previously presented prove that this is indeed the case. In particular, the following conclusions may be drawn:

1. A large majority of current myoelectric prosthesis users have at least some degree of hand or prehensor interruption or loss of control;
2. Electrode contact security is directly linked to the efficacy in providing hand or prehensor control, significantly more so than overall socket fit;
3. Housing units that ensure secure electrode-to-skin contact are not being employed within current prostheses;
4. The use of external devices to improve electrode-to-skin contact within prosthetic sockets can significantly improve prosthesis functionality;
5. The use of a bespoke housing design can be implemented that will significantly improve prosthesis functionality;
6. Electrode alignment can alter prosthesis functionality;
7. Electrode alignment and contact security will vary depending on the skill and experience of the Prosthetist;
8. Specific upper limb daily living movements and activities performed by the prosthesis user may result in the production of motion artifacts in fairly defined patterns.

Although limitations and potential errors have been recognised throughout the thesis, the evidence still demonstrates that improvements to myoelectric prosthesis functionality can be facilitated in this area. The null hypothesis, that the socket and the electrode housings do not significantly affect prosthesis functionality within standard socket designs, can be rejected. These factors listed above are clearly related to the role of the Prosthetist and the adjustability of current devices associated with socket-housed electrodes which can assist prosthesis usage and functionality.

There are a number of areas for consideration that have been highlighted as a result of this study. Firstly, it is clear that there are significant variations between the levels of prosthesis response and control available to a broad band of myoelectric prosthesis users and that these variations can be linked to electrode contact tightness and socket tightness. Significantly, this study has shown that improving electrode contact tightness locally over the electrode site, rather than just increasing the overall socket tightness, is more likely to improve myoelectric prehensor or hand response.

The evidence from this study also suggests that movements occurring between the interface of the electrode and the residual limb, particularly during the completion of daily tasks, can affect the functionality of the prosthesis, particularly if optimal contact fit for this interface is not provided within the socket via the initial casting, rectification and manufacturing procedures. Although a link between poor functional response and electrode contact may appear to be rudimentary, the key element for consideration is the fact that no functional analysis with regard to socket movement and the maintenance of electrode contact appears to have been undertaken prior to this study. In addition, no analyses with regard to how this relates to the capability of the prosthesis user to complete normal daily living activities has been undertaken, and how this affects overall prosthesis usage.

Furthermore, anecdotal evidence suggests that few significant design alterations or implementations have been with included within current clinical practise with regard to socket types (which have apparently changed little in real terms since the early 1960s) or the method of securing electrode contact devices, which again have changed little since the inception of myoelectric control.

It was important to maintain validity with respect to the requirements of the upper limb prosthesis user throughout each part of the study. For this reason, the activities of daily living were an integral part of each assessment, since these have been validated as representative of the actions and uses of the upper limb that would most normally be undertaken (82). However, function is clearly not the only consideration for upper limb prosthesis users. **Chapter 3** highlights the fact that although a very large majority of myoelectric prosthesis users appear to have some degree of impaired function emanating from interruptions with prehensor activation and control; this does not prevent long term wear during the day. These correlations tend to support the fact that myoelectric prostheses

offer a combination of function and cosmesis, particularly when considering that most users preferred the myoelectric prosthesis overall, but not for purely functional use.

In addition, current practice for acquiring the myoelectric signals for prosthesis control differs significantly from the overall accepted best practice for myoelectric signal acquisition in other related fields (170). One key condition, electrode contact security, was highlighted within **chapter 4**. Although the prescribed best practice for signal acquisition involves adhering the electrode to the skin, the same improvements to signal acquisition may be achieved by using external devices attached to the socket which can enhance electrode to skin contact. Although the use of electrolytic paste to aid signal conduction is also recommended, the use of paste in conjunction with current socket-housed electrodes could encourage more electrode movement with respect to the skin, thereby negating any positive effect (170). This process could therefore not at present be recommended.

Aesthetic appeal is an extremely important facet in prosthesis usage, again borne out in **chapter 3** by the numbers of users who have employed their prostheses for socialising. For this reason, it is important to consider the design implications of any future device that may be integrated within the electrode housing mechanism to potentially improve functional capability. The implementation of a relatively simple, bespoke electrode housing device (**chapter 5**) has been shown to improve levels of functionality within what is still a relatively small group of subjects. However, the device used within this study does have some quite obvious aesthetic limitations and the cost / benefit analysis to a potential user of using a similar component, an overriding factor when considering prosthesis usage, cannot be ignored. Nevertheless, the myoelectric prosthesis is primarily designed for functional usage (72). Including restrictions to its functional capabilities for purely cosmetic reasons requires careful consideration, not least because of the high costs involved in the prescription of myoelectric prostheses.

The device used within this study (in **chapter 5**) was simple and inexpensive, yet it provided enhanced electrode placement, alignment and contact security and useful adaptability that improved user functionality. Implementing adjustable components that can affect greater prosthesis control and function is common practice within lower limb prostheses; adjustable alignment devices are used extensively within modern modular systems, enabling fine tuning of prosthetic function and subsequent user control to be

achieved by the Prosthetist. Even when the initial set-up is incorrect, the Prosthetist may still be able to acquire effective electrode alignment and prosthesis functionality with the use of these devices. There is at present no similar, clinically-available adjustable electrode housing device, meaning that myoelectric signal acquisition and subsequent prosthesis functionality is therefore still very much reliant on the optimal assessment and casting skills of the Prosthetist, and to some extent the manufacturing skills of the technician.

Ideally, any and all Prosthetists should inherently be able to produce a well-fitting socket, which consistently meets the requirements of the prosthesis user. The use of transparent check sockets has been widely reported, which can enable a more intimate socket fit to be established (72). However, the evaluation of check sockets is a skill in itself, and there is no guarantee that these sockets will always be available, as they are time consuming and increase expense. In addition, this study (within **chapter 3**) has shown that it is local electrode contact intimacy, rather than just overall socket intimacy, that will have a more significant effect on prosthesis functionality and hand or prehensor control.

Identifying key aspects of prosthesis improvement is only part of this story, however. Even within this study, where the Prosthetist was relatively experienced, it has been shown that the use of an adjustable electrode housing device can increase prosthesis functionality significantly. The author's initial desire to complete a PhD in this area was directly linked to the large variations in functional myoelectric hand control available from sockets produced by student Prosthetists, and how these may be greatly improved by alterations and adaptations improvised within the educational facility, but not clinically viable in practice. Prosthetist education and experience, particularly with regard to upper limb prostheses, has changed markedly over recent years. This is a crucial factor to consider when reporting on socket fit and electrode contact and its role in prosthesis functionality, since Prosthetist capability is inherently linked to this. Information regarding this area is provided within **Appendix E**-*the changing education of Prosthetists*.

This study has confirmed that the fit of the socket, and particularly the electrode contacts, is the most crucial element within the prosthesis with regard to prosthesis functionality. This in turn is reliant on the skills of the Prosthetist. This study has shown that a device offering post-delivery adjustments can be used to enhance prosthesis functionality.

7.1.1 *Future research*

This study has highlighted a number of factors that can affect signal acquisition and myoelectric prosthesis usage. Socket motion without improved contact security, the employment of specific types of sockets and electrode housing components, and the motions and movements employed by the user have all been shown to have an impact on myoelectric prostheses responsiveness and ultimate functionality, to varying levels and under various conditions. These are however by no means the only factors that could affect myoelectric functionality and usage. The evidence provided here, as well as from other studies, also suggests that absolute contact pressure, distinct tasks and movements and other contact factors such as impedance and impurities on the skin may also have an effect on prosthesis functionality. With this in mind, the following proposals could be considered for further study:

1. An investigation into the absolute electrode-to-skin contact pressure that would result in improved myoelectric prosthesis functionality.
2. An investigation into the relative motions of each of the upper limb joints, within each activity of daily living, and the resultant motion of the socket within respect to the residual limb.
3. An investigation into the effect of surface impedance with regard to the acquisition of the myoelectric signal.

In addition, the development of an electrode housing unit that could meet user requirements within an acceptable aesthetic format is worth exploring. Although socket movement with respect to the skin does appear to influence the production of motion artifacts, local implementation of an adjustable housing unit does negate these effects and improves functional response on a par with those that would be associated with signal acquisition best practice. With some creative input and a reasonable funding stream for further research, a more usable housing unit nay be available that could improve levels of prosthesis functionality without resorting to complete socket prescription changes which may not be suitable for the prosthesis user. In addition, certain groups of prosthesis users, such as children, with varying residual limb volume, and developing muscles which could affect electrode contact, could particularly benefit from the inclusion of an adjustable electrode housing unit.

There are obviously many reasons why myoelectric signal acquisition is likely to cause problems in terms of prosthesis functionality. It is not always a smooth, effort-proportional signal at source, even before it reaches the skin's surface, during which time it is likely to be absorbed within surrounding tissues. It may be obscured by other myoelectric signals being produced from muscles within the vicinity. At this point, mechanical factors and movements between the electrode and the residual limb, together with tiring muscles and heavy componentry, will all affect signal quality and prosthesis response. Inevitably, each factor must be identified and effective research undertaken to find the most useful way of delivering a usable signal that is unaffected by other factors.

7.2 *Specific original work within these investigations*

7.2.1 *The bespoke electrode housing unit*

The use of the bespoke electrode housing unit (**chapter 5**) proved successful in enabling greater levels of apparent functionality from most of the prosthesis users employed within the study. However, the provision of the housing was not without its difficulties, which included the following:

1. Securing the housing effectively onto the socket and contouring the material to fit was problematic and time consuming.
2. The level of contact security required feedback from the prosthesis user; there was no exact measurement of pressure that would have been able to link the contact variations with improvements in prosthesis functionality.
3. The aesthetic considerations of the housing should be noted; on a relatively small prosthetic socket, it is unlikely that a unit in a similar format would be acceptable to the majority of prosthesis users, albeit if it provides an improvement in functional usage.
4. The alignment variations were fixed into maximum rotational differentials from the accepted standard position. Any definitive device would ideally require finite alignment adjustment capabilities allowing very small changes to be made and the electrode secured within these new positions.

With myoelectric assessment systems such as the 'Myoboy', it may be assumed that even the most inexperienced Prosthetist should be able to ascertain the correct electrode positions for effective myoelectric control. However, there are a number of factors that need

to be considered, even accepting that the ‘Myoboy’ is indeed an extremely sophisticated and accurate assessment tool:

1. As with any clinical technique, component or assessment system, training and education is required with the ‘Myoboy’ system if it is to be suitably employed for accurate signal acquisition. Even following a period of training, continuous usage (or practice) is clearly beneficial for the Prosthetist for accurate assessments to be maintained.

2. With the erratic nature of the myoelectric signal being depicted in **chapter 4**, and muscle fatigue and the resultant non-linearity of the myoelectric signal over relatively short time periods being highlighted in **chapter 2**, it becomes clear that acquiring the best electrode position on a muscle site from a standard assessment is not straightforward. Either or both of these factors could influence the decision making process with regard to the location and alignment of the electrode contacts.

3. The ‘Myoboy’ system is relatively expensive; if a clinic or clinical centre has very few myoelectric prosthesis users, it may be viewed as financially unviable to acquire a ‘Myoboy’, particularly where funding restrictions apply. This would then leave the Prosthetist to determine the best signal acquisition points from a myoelectric hand or other prehensor, which is much less accurate.

The above factors would clearly lead to the potential misplacement or misalignment of the electrode unit. In addition, current plaster cast rectification techniques employed within current clinical prosthetic practice rely on the accurate relocation of the identified electrode site onto the positive cast or model. Furthermore, the amount of cast reduction, both volumetric for overall socket fit and particularly over the electrode contact site(s), is again within the remit of the Prosthetist. As witnessed in **chapter 3**, even if the socket is apparently loose, a securely fitting electrode or electrodes may still lead to reliable hand or prehensor function which is rarely restricted by either unwanted activation or poor response. Failing this, the implementation of a housing device such as that tested within **chapter 6** can alleviate contact problems which have developed as a result of incorrect plaster rectification over the electrode contact sites.

The socket itself, although not apparently as important as the electrode contact sites in light of the results from **chapter 3** and **chapter 5**, still has some effect in terms of prehensor control. The determination of the security of the socket will rely again on the skill of the Prosthetist, assessing the consistency of the tissues remaining within the residual limb and producing a cast that and rectification plan that attains suitably firm contact between this and the socket. Additionally, the choice of socket type will also have an effect on the movement characteristics that occur during usage.

The choice of socket type and subsequent modification will depend on a number of factors during the assessment (4):

1. The level of limb absence
2. The length of the residual limb
3. The consistency of the tissues within the residual limb
4. The shape of the residual limb
5. The experience of the Prosthetist
6. The personal preference of the Prosthetist
7. The personal preference of the prosthesis user

The shape of the socket and its volumetric match to the residual limb will determine the stiffness of the contact between the socket and the residual limb, and hence the prosthesis, during usage. The use of check sockets will enhance the likelihood of a suitable fit- however; the check socket material will need to be of a similar stiffness to the finished socket material. Otherwise, the fit of the check socket may not reflect the ultimate fit of the finished socket. The stiffness of check socket materials may vary considerably, from very stiff ('Northplex') (271) to relatively flexible ('Surlyn') (272). It is important that these factors are considered prior to the evaluation of each socket fit.

7.2.2 *Daily living activities and the production of motion artefacts*

Results from this study (**chapter 6**) suggest that the choice of socket will have an effect on the movement that occurs during motions associated with the activities of daily living, but only significantly within certain types of activities or upper limb motions. The 'Munster' socket, often quoted as the socket of choice for myoelectric fittings (28, 117), would not appear to restrict the production of motion artifacts more effectively than the

‘Hybrid supracondylar’ socket for limbs with a relatively short length. For longer residual limbs, the North-Western supracondylar’ socket (37) appeared to affect motion artifacts on the ‘open’ function of the myoelectric hand but it should be noted that the small number of prosthesis user subjects would obviously affect these results. However, many similar investigations regarding upper limb prostheses and some for lower limb prostheses have relied solely on the input of a single subject.

The socket is clearly a key element within the upper limb myoelectric prosthesis. Variations in its design will lead to changes in the associated performance of the prehensor and will affect the overall functionality of the myoelectric hand or prehensor, based on the use of the SHAP assessment undertaken within this study (**chapters 5** and **6**). In addition, all of the sockets used in this study are clearly more susceptible to movements which are undertaken in specific daily living activities. Furthermore, if these activities involve the moving or transferring of objects over a specific weight, found to be between 0.5Kg and 1Kg from the results of this study, then a significant level of motion artifact production becomes apparent (**chapter 4**). The motion artifacts acquired at weights of 1Kg were of a similar or larger size than those that the equivalent user would normally be able to produce to control the prosthesis. Therefore, it would be logical to assume that these artifacts would interfere with the control of the hand or prehensor.

Training the myoelectric prosthesis user is clearly important in terms of improving functional prosthesis usage and increasing the chances of user satisfaction and prosthesis retention. The multi-professional team approach to rehabilitation ensures that the therapist experienced in this type of training will provide invaluable expertise and assistance to the myoelectric prosthesis user, particularly at early stages of limb wear (264). However, some evidence still suggests that there is inadequate training of therapists associated with prosthetic rehabilitation (120). This study has also shown that improvements in the functional usage of the prosthesis may not only be acquired through practice and a general improvement of prehensor control acquired over a time period, as suggested previously (44). Moreover, from **chapter 6**, it is clear that prosthesis usage involving certain types of movements, and the lifting or transferring of weights and objects over and above certain values, significantly increases the production of motion artifacts.

What is also clear is that these artifacts are relatively similar or indeed larger in size and duration than the equivalent myoelectric signal produced by the corresponding prosthesis user during normal hand or prehensor activation. Consequently, it would therefore be reasonable to suggest that the movements highlighted within this study, such as the hand to hip pocket movement, will have a requisite increase in false prehensor or hand operation. This in turn would then lead to a reduction in prehensor control for these specific movements and movements involving an increase in object weight. For these reasons, it may be reasonable to suggest that specific training may also be appropriate to provide the prosthesis user with information regarding the types of movements and activities that the myoelectric prosthesis would best be suited. Failure to do this could potentially lead to the user rejecting their prosthesis for functional usage overall because they have had problems within achieving tasks that are inherently prone to poor control through socket movements and subsequent artefact production.

The use of socket types with enhanced suspension has been highlighted by various authors, with a view to improving functional capabilities through enhanced electrode security and contact with the skin of the residual limb. However, socket types that have been offered as alternatives to the standard socket designs used in this study, such as roll-on sockets, are not without their own drawbacks and limitations. These sockets are not suitable for many prosthesis users because of various reasons, ranging from the size and more importantly the shape of the residual limb, to cognitive issues and donning and doffing problems. Therefore, although these socket types are purported to be significant in terms of their improvements to prehensor and hand function, they are not suitable for all prosthesis users. Local intervention over the electrode contact sites, without the need for new sockets or other significant alterations, could enhance electrode contact and improve functionality for prosthesis users such as these in particular. Again, results throughout this thesis show that local intervention and improvements to electrode contact security offer relatively greater improvements in hand or prehensor control and prosthesis functionality than similar improvements to overall socket intimacy and fit.

The principle of making numerous adjustments post-prosthesis delivery is one which is applied effectively to lower limb prostheses (11, 115, 133, 240). Although the subject of this study has focused primarily around transradial limb absence and associated prosthesis users, it many respects it becomes even more significant for potential myoelectric prosthesis

users at more proximal levels of limb absence. Sockets traditionally fitted at these levels are often not as secure as those fitted at the transradial level (**chapter 3**) and as such are inherently more likely to be affected by motion between the socket and the skin of the residual limb. The user pool for myoelectric prostheses at more proximal levels are particularly low-however, there would still appear to be some users who can produce effective functional usage from their myoelectric prostheses.

There is some anecdotal evidence to suggest that these users acquire their prostheses from private clinics or facilities, where Prosthetists may be more experienced in fitting state of the art technology and also have more time to produce numerous socket adjustments should these be required. Unfortunately, the numbers of available users to participate in any usage study is tiny, and it appears that this is unlikely to change unless significant improvements are made to prostheses for these levels. Frustratingly, these improvements will not be as likely to occur without the necessary research which would of course normally involve more subjects being involved.

7.3 *Overall thesis summary*

This study investigated a here-to relatively small prosthesis element in terms of previous research, namely socket and electrode contact, with a large group of associated variables, but was still able to identify areas for development that would significantly improve the control of myoelectric prostheses. At a time when new technical improvements are being made through multi-functional limbs, such as the I-Limb, gaining consistent levels of control is paramount if full use is to be extracted from these new technologies.

It has been stated anecdotally, and within prosthetic conferences and groups, that control and acquiring greater degrees of prehensor response is now the key element with regard to improving myoelectric prosthesis uptake and usage. The myoelectric prosthesis, like any device, is only as effective as its weakest link will allow. This link is the transition between the signal at source and its uptake within the myoelectric processor. For what would ostensibly be a relatively small price, including some basic changes to the provision of sockets, electrode housing and training, the lives of upper limb prosthesis wearers could be significantly improved. In addition, the training of myoelectric prosthesis users could be enhanced if the potential prosthesis user could be educated with respect to the movements that were more likely to interfere with prehensor or hand control. If the user was able to

acquire more control, and was aware of the limitations to usage and which actions were better suited to myoelectric activation and functionality, then successful rehabilitation with these devices could be improved, and rejection rates reduced.

A Questionnaire on Myoelectric prostheses: a survey of their use, and usefulness

Hello and thank you for taking the time to complete this questionnaire. The questions below form part of an ongoing study designed to investigate the usefulness of myoelectric prostheses. The information gathered may be used in scientific journals and conference presentations. Please answer these questions as truthfully as you can. If you are not sure, then please write 'not sure' next to your answer.

Thank you once again.

Section A : A few questions about you

1) What is your gender? *Please circle.*

Male	Female

2) What is your date of birth? ……

3) What was the date of your amputation? (if your limb has been absent from birth, please write 'as above')

……..…

4) What was the cause of your amputation?

……..

5) Do you live on your own?

Yes	**No**

Please continue now by filling in section B and section C

Section B

1) How long have you had your myoelectric prosthesis?
Please circle

More than 10 years	5-10 years	1-5 years	Less than 1 year

2) Do you continue to use your myoelectric prosthesis? *Please circle*

Yes **Please continue**	No **Please go to Section d**

3) How many days a week do you use the myoelectric prosthesis?
……..…

4) On the days that you use the myoelectric prosthesis, for how many hours do you usually wear it?
……..

5) When do you use your myoelectric prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the myoelectric prosthesis	I always do this **without** the myoelectric prosthesis	I do this **with and without** the myoelectric prosthesis	I don't do this
Work inside				
Work outside				
Play sports				
Socialise / go out				
Carry shopping				
Gardening				
Please specify any other activities that you do with the myoelectric prosthesis				

6) Have you had experience of using a body –powered prostheses in addition to your myoelectric prosthesis? *Please circle.*

Yes **Please continue**	No **Please go to Section c**

7) When do you use / did you use your body-powered prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the body-powered prosthesis	I always do this **without** the body-powered prosthesis	I do this **with and without** the body-powered prosthesis	I don't do this
Work inside				
Work outside				
Play sports				
Socialise / go out				
Carry shopping				
Gardening				
Please specify any other activities that you do with the body-powered prosthesis				

8) Which of the two types of prosthesis, body-powered or myoelectric, would you consider being the most functional? *Please circle*

Body-powered	**Myoelectric**

9) Which prosthesis has the best overall features, i.e. cosmesis and comfort? *Please circle*

Body-powered	**Myoelectric**

Section C : About your socket

1) Please rate the **general fit** of your myoelectric socket on the scale below, by marking it with a small 'x'. The nearer you put the 'x' to the word 'tight', the tighter you feel the socket is.

Very loose=0_____10=Very tight

2) Please rate the fitting of the **electrodes** within your myoelectric socket on the scale below by marking it with a small 'x'. The nearer you put the 'x' to the word 'tight', the tighter you feel the electrodes are over your skin when you are wearing the socket.

Very loose= 0_____10=Very tight

3) Does the socket on your myoelectric prosthesis feel different to that of your cosmetic prosthesis? *Please circle.*

Yes **Please continue**	No/don't have a cosmetic prosthesis **Please go to question 5**

4) If 'yes' then please tick the appropriate box(es) below, indicating why this may be the case.

Myoelectric socket feels 'tighter'	
Myoelectric socket feels more loose	
Myoelectric socket feels less comfortable	
Myoelectric socket feels more comfortable	
Myoelectric socket feels heavier	
Myoelectric socket feels lighter	

5) Does the myoelectric hand / terminal device sometimes work ‘on its own’ i.e. without you actively trying to operate it? *Please tick*

Yes, often	
Sometimes	
Rarely	
Never	

6) Does the myoelectric hand / terminal device sometimes **not work** when you are actively trying to operate it? *Please tick*

Yes, often	
Sometimes	
Rarely	
Never	

7) Does the myoelectric prosthesis become easier or more difficult to operate during the day? *Please circle the appropriate answer for each part of the day.*

Morning	**Easier**	**The same**	**More difficult**
Afternoon	**Easier**	**The same**	**More difficult**
Evening	**Easier**	**The same**	**More difficult**

8) Does your stump swell during the day if the prosthesis is not worn? *Please circle.*

Yes	**No**

Users who still wear their myoelectric prostheses should not complete section D.

Section D: *To be completed only by those users who no longer wear their myoelectric prosthesis*

1) How long did you have your prosthesis before you rejected it?
Please circle.

More than 10 years	5-10 years	1-5 years	Less than 1 year

2) Do you use any other functional prostheses? *Please circle*

Yes, body-powered	**Yes, other**	**No**

If 'other' please state which type…….

3) Why did you decide to no longer wear your myoelectric prosthesis? Please select from the reasons listed below. Place them in order of importance, from '1' (most important) to '5' (least important).

Reason	**Importance (number 1-5)**
Lack of function	
Discomfort	
Weight	
No wrist unit	
Uncosmetic	
Other *Please specify* ……	

Thank you for taking the time to complete this questionnaire

A Questionnaire on Myoelectric prostheses: a survey of their use, and usefulness

Hello and thank you for taking the time to complete this questionnaire. The questions below form part of an on-going study designed to investigate the usefulness of myoelectric prostheses. The information gathered may be used in scientific journals and conference presentations. Please answer these questions as truthfully as you can. If you are not sure, then please write 'not sure' next to your answer.

Thank you once again.

Section A : A few questions about you

1) What is your gender? *Please circle.*

Male	Female

2) What is your date of birth? ……

3) What was the date of your amputation? (if your limb has been absent from birth, please write 'as above')

……..…

4) What is the level of your limb absence i.e. Below elbow, Above Elbow?

……..

5) What was the cause of your amputation?

……..

6) Do you live on your own (please circle)?

Yes	**No**

Please continue now by filling in section B and section C

Section B

1) How long have you had your myoelectric prosthesis?
Please circle

More than 10 years	5-10 years	1-5 years	Less than 1 year

2) Do you continue to use your myoelectric prosthesis? *Please circle*

Yes **Please continue**	No **Please go to Section d**

3) How many days a week do you use the myoelectric prosthesis?
……..…

4) On the days that you use the myoelectric prosthesis, for how many hours do you usually wear it?
……..

5) Are you aware of the type of myoelectric prosthesis that you have?
Please circle

Steeper	**Otto Bock**	**Other / Not sure**

6) When do you use your myoelectric prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the myoelectric prosthesis	I always do this **without** the myoelectric prosthesis	I do this **with and without** the myoelectric prosthesis	I don't do this
Work inside e.g. use and active grip, performing indoors any of the following or similar				
Holding objects				
Opening bottles				
Tying laces				
Turning pages of a book				

Work outside e.g. use an active grip, performing outdoors on any of the following or similar				
Hold garden tools				
Pick up bags of sand/soil				
Wash a car				
Use a drill				
Play sports				
Socialise/go out				
Please specify any other activities that you do with the cosmetic prosthesis				

7) When do you use / did you use your cosmetic prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the cosmetic prosthesis	I always do this **without** the cosmetic prosthesis	I do this **with and without** the cosmetic prosthesis	I don't do this
Work inside e.g. use and active grip, performing indoors any of the following or similar				
Holding objects				
Opening bottles				
Tying laces				
Turning pages of a book				
Work outside e.g. use an active grip, performing outdoors on any of the following or similar				
Hold garden tools				
Pick up bags of sand/soil				
Wash a car				

Use a drill				
Play sports				
Socialise/go out				
Please specify any other activities that you do with the cosmetic prosthesis				

8) Have you had experience of using a body –powered prostheses in addition to your myoelectric prosthesis? *Please circle.*

Yes **Please continue**	No **Please go to Section c**

If the answer to the above is 'No' then please go to section 'C'.

9) When do you use / did you use your body-powered prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the body-powered prosthesis	I always do this **without** the body-powered prosthesis	I do this **with and without** the body-powered prosthesis	I don't do this
Work inside e.g. use and active grip, performing indoors any of the following or similar				
Holding objects				
Opening bottles				
Tying laces				
Turning pages of a book				
Work outside e.g. use an active grip, performing outdoors on any of the following or similar				
Hold garden tools				
Pick up bags of sand/soil				

Wash a car				
Use a drill				
Play sports				
Socialise/go out				
Please specify any other activities that you do with the cosmetic prosthesis				

10) Which of the two types of prosthesis, body-powered or myoelectric, would you consider being the most functional? *Please circle*

Body-powered	**Myoelectric**	**Cosmetic**

11) Which prosthesis has the best overall features, i.e. Function, cosmesis and comfort?
Please circle

Body-powered	**Myoelectric**	**Cosmetic**

Section C : About your socket

1) Please rate the **general fit** of your myoelectric socket on the scale below, by placing a ring around the appropriate number: the ***lower*** the number, the ***looser*** the fit.

1 2 3 4 5 6 7 8 9 10

2) Please rate the fitting of the **electrodes** within your myoelectric socket on the scale below by placing a ring around the appropriate number: the ***lower*** the number, the ***looser*** the fit.

1 2 3 4 5 6 7 8 9 10

3) Does the socket on your myoelectric prosthesis feel different to that of your cosmetic prosthesis? *Please circle.*

Yes **Please continue**	No/don't have a cosmetic prosthesis **Please go to question 5**

4) If 'yes' then please tick the appropriate box(es) below, indicating why this may be the case.

Myoelectric socket feels 'tighter'	
Myoelectric socket feels more loose	
Myoelectric socket feels less comfortable	
Myoelectric socket feels more comfortable	
Myoelectric socket feels heavier	
Myoelectric socket feels lighter	

5) Does the myoelectric hand / terminal device sometimes work 'on its own' i.e without you actively trying to operate it? *Please tick*

Yes, often	
Sometimes	
Rarely	
Never	

6) Does the myoelectric hand / terminal device sometimes **not work** when you are actively trying to operate it? *Please tick*

Yes, often	
Sometimes	
Rarely	
Never	

7) Does the myoelectric hand not function as effectively when you straighten or flex your elbow? Which, if any, of the following positions does the hand not work as effectively?

Arm straight	**Elbow partly flexed (bent)**	**Elbow fully flexed**

8) Does the myoelectric prosthesis become easier or more difficult to operate during the day? *Please circle the appropriate answer for each part of the day.*

Morning	**Easier**	**The same**	**More difficult**
Afternoon	**Easier**	**The same**	**More difficult**
Evening	**Easier**	**The same**	**More difficult**

9) Does your stump swell during the day if the prosthesis is not worn? *Please circle.*

Yes	**No**

Users who still wear their myoelectric prostheses should not complete section D.

Section D: *To be completed only by those users who no longer wear their myoelectric prosthesis*

3) How long did you have your prosthesis before you rejected it?
Please circle.

More than 10 years	5-10 years	1-5 years	Less than 1 year

4) Do you use any other functional prostheses? *Please circle*

Yes, body-powered	Yes, other	No

If ‘other’ please state which type…….

3) Why did you decide to no longer wear your myoelectric prosthesis? Please select from the reasons listed below. Place them in order of importance, from ‘1’ (most important) to ‘5’ (least important).

Reason	**Importance (number 1-5)**
Lack of function	
Discomfort	
Weight	
Uncosmetic	
Other *Please specify* ……	

Thank you for taking the time to complete this questionnaire

A Questionnaire on Myoelectric prostheses: a survey of their use, and usefulness

Hello and thank you for taking the time to complete this questionnaire. The questions below form part of an ongoing study designed to investigate the usefulness of myoelectric prostheses. Please answer these questions as truthfully as you can. If you are not sure, then please write 'not sure' next to your answer.

Thank you once again.

Section A : A few questions about you

1) What is your gender? *Please circle.*

Male	Female

Acceptable	✓	Unacceptable	
Comments / suggestions			

2) What is your date of birth? .....

Acceptable	✓	Unacceptable	
Comments / suggestions			

3) What was the date of your amputation? (if your limb has been absent from birth, please write 'as above')

.....

Acceptable	✓	Unacceptable	
Comments / suggestions			

4) What was the cause of your amputation?

.....

Acceptable	✓	Unacceptable	
Comments / suggestions			

5) Do you live on your own?

Yes	No

Acceptable	✓	Unacceptable	
Comments / suggestions			

Please continue now by filling in section B and section C

Section B

1) How long have you had your myoelectric prosthesis?

More than 10 years	5-10 years	1-5 years	Less than 1 year

Acceptable	✓	Unacceptable	
Comments / suggestions			

2) Do you continue to use your myoelectric prosthesis? *Please circle*

Yes **Please continue**	No **Please go to Section 6**

Acceptable	✓	**Unacceptable**	
Comments / suggestions COULD SAY GO STRAIGHT TO BACK PAGE. EASIER TO FIND			

3) How many days a week do you use the myoelectric prosthesis?
.....

Acceptable		**Unacceptable** ✓	
Comments / suggestions			

4) On the days that you use the myoelectric prosthesis, for how many hours do you usually wear it?
.....

Acceptable		**Unacceptable** ✓	
Comments / suggestions			

5) When do you use your myoelectric prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the myoelectric prosthesis	I always do this **without** the myoelectric prosthesis	I do this **with and without** the myoelectric prosthesis	I don't do this
Work inside				
Work outside				
Play sports				
Socialise / go out				
Carry shopping				
Gardening				
Please specify any other activities that you do with the myoelectric prosthesis				

Acceptable		**Unacceptable**	
Comments / suggestions DO YOU WANT THEM TO GIVE EXAMPLES OF WORK, SPORT ETC IF SO MORE SPACE NEEDED.			

6) Have you had experience of using a body –powered prostheses in addition to your myoelectric prosthesis? *Please circle.*

Yes **Please continue**	No **Please go to Section c**

Acceptable		**Unacceptable**	
Comments / suggestions			

7) When do you use / did you use your body-powered prosthesis? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the body-powered prosthesis	I always do this **without** the body-powered prosthesis	I do this **with and without** the body-powered prosthesis	I don't do this
Work inside				
Work outside				
Play sports				
Socialise / go out				
Carry shopping				
Gardening				
Please specify any other activities that you do with the body-powered prosthesis				

Acceptable	✓	**Unacceptable**	
Comments / suggestions			

8) Which of the two types of prosthesis, body-powered or myoelectric, would you consider being the most functional? *Please circle*

Body-powered	**Myoelectric**

Acceptable		**Unacceptable**	
Comments / suggestions MOST FUNCTIONAL OR MOST USEFUL			

Ask a user — the q. is the understanding of 'functional' h

9) Which prosthesis has the best overall features, i.e. cosmesis and comfort?
Please circle

Body-powered	Myoelectric

Acceptable		Unacceptable	
Comments / suggestions SPACE FOR COMMENTS.			

Section C : About your socket

1) Please rate the **general fit** of your myoelectric socket on the scale below by marking it with a small 'x'. The nearer you put the 'x' to the word 'tight', the tighter you feel the socket is.

Tight_____loose

Acceptable		Unacceptable	
Comments / suggestions PUT MYOELECTRIC IN BOLD AS THEY HAVE JUST BEEN COMPARING MYO - BP.			

2) Please rate the fitting of the **electrodes** within your myoelectric socket on the scale below by marking it with a small 'x'. The nearer you put the 'x' to the word 'tight', the tighter you feel the electrodes are over your skin when you are wearing the socket.

Tight_____loose

Acceptable		Unacceptable	
Comments / suggestions			

3) Does the socket on your myoelectric prosthesis feel different to that of your cosmetic prosthesis? *Please circle.*

Yes **Please continue**	No/don't have a cosmetic prosthesis **Please go to question 5**

Acceptable		**Unacceptable**	
Comments / suggestions			

4) If 'yes' then please tick the appropriate box(es) below, indicating why this may be the case.

Myoelectric socket feels 'tighter'	
Myoelectric socket feels more loose	
Myoelectric socket feels less comfortable	
Myoelectric socket feels more comfortable	
Myoelectric socket feels heavier	
Myoelectric socket feels lighter	

Acceptable		**Unacceptable**	
Comments / suggestions			

5) Does the myoelectric hand / terminal device sometimes work 'on its own' i.e without you actively trying to operate it? *Please tick*

Yes, often	
Sometimes	
Rarely	
Never	

Acceptable		**Unacceptable**	
Comments / suggestions			

6) Does the myoelectric hand / terminal device sometimes **not work** when you are actively trying to operate it? *Please tick*

Yes, often	
Sometimes	
Rarely	
Never	

Acceptable		**Unacceptable**	
Comments / suggestions			

Appendix A-*Questionnaires and Questionnaire development: patient information sheet*

Directorate of Prosthetics and Orthotics, University of Salford

Patient Information Sheet

Analysis of socket design in myoelectric prostheses: Survey questionnaire

You are being invited to take part in a research study to help us learn more about important issues related to the successful provision of myoelectric prostheses. Before you decide, it is important for you to understand why the research is being done and what it will involve. This document provides you with important information about the purpose and benefits of participating in the study.

Please take time to read the following information carefully. If you do decide to complete the

BACKGROUND TO THE STUDY

We know that many people find using a myoelectric prosthesis difficult, and are sometimes frustrated that their prosthesis does not work as effectively as they would like. For some people, there can be difficulties with carrying out many normal daily activities, such as reaching and grasping objects, using their myoelectric prostheses. The main objective of this research study is to investigate the role that the socket plays in the overall usability of myoelectric prostheses during normal daily activities. We plan to use this information to guide the development of myoelectric sockets that will maximize the benefits of myoelectric prostheses. We also hope that gathering this data will help our understanding of the importance of electrode contacts within the socket and what happens to them during prostheses use.

CONFIDENTIALITY OF SUBJECT RECORDS

All information which is collected during the course of the research will be kept strictly confidential.

What will happen to the results of the research study?
Research findings will be made available to you upon request.

CONTACT INFORMATION

For more information about the study contact:
John Head, directorate of prosthetics and orthotics, Brian Blatchford Building, University of Salford, Salford, M6 6PU. Phone: (0161)-295-2303; Fax: (0161)-295-2668; Email: J.Head@salford.ac.uk

THANK YOU VERY MUCH FOR TAKING TIME TO READ THIS DOCUMENT,AND IF YOU CAN, TO COMPLETE THE QUESTIONNAIRE!

Analysing the relationship between socket design and low levels of functionality in myoelectric prostheses: A prosthesis user questionnaire

1. Introduction

This protocol relates to one of a series of investigations designed to assess the efficacy of current prosthetic interface (socket) designs with regard to myoelectric prostheses functionality. Myoelectric prostheses use electromyographic (EMG) signals from residual limb muscles encapsulated within the prosthetic socket to operate electrically powered prehensors. These EMG signals are picked up via electrodes that are housed within the inner wall of the socket. The ultimate goal of the work is to ascertain if current socket designs allow motion to occur between these electrodes and the residual limb, and if this motion inhibits functional usage and ultimate prosthetic functionality.

This particular part of the study involves the distribution of a carefully constructed questionnaire to known myoelectric prostheses users, seeking information regarding their prosthesis usage rates, socket types and fit, and any problems with usage that they may have encountered that could be related to electrode contact problems within the socket. The information gathered would be used to construct a data base of responses that could show if a link between socket design, electrode contact and prosthesis usage and functionality exists. This could then be used to supplement other data being gathered around this subject area and ultimately lead to improvements in the provision of prosthesis components and design, leading to greater and more effective functional usage for upper limb myoelectric prosthesis wearers.

2. Scientific background

According to the National Amputee Statistical Database, there were 267 new upper limb amputees and 88 new referrals of upper limb congenital cases between 2004/2005 [1]. The majority of these were at either the transradial or transhumeral levels of limb absence. Most amputations of the upper limb occur due to traumatic injury. The reasons for congenital limb absence are more complex, and are still not completely understood.

The loss of all or part of an upper limb is extremely detrimental to a person's physical and psychological well-being. The natural upper limb has an excellent command and control structure, an effective and extremely mobile segmented limb, and a highly dextrous manipulator in the form of the hand, which is able to perform numerous tasks promptly and effectively. At present, replacing these elements prosthetically is very difficult to achieve. Current functional alternatives use to control prehensors are either:

1) Body-powered, using a cumbersome harness and biomechanical control, or
2) Myoelectrically operated, using EMG signals generated within residual limb musculature.

The former, although uncosmetic, restrictive and outdated, still remain the most functional type of prosthesis, despite being largely unchanged in design for almost a century. The advantages offered by self-contained, myoelectric prostheses suggest that these should be far more popular than body-powered prostheses. However, survey results have not shown this to be the case [2, 3, 4, 5, 6].

3. Usage rates for myoelectric prostheses

More modern myoelectric prostheses are, according to survey results collated over the last twenty years, significantly less able to offer users the same level of prosthetic functionality as body-powered prostheses **(see Figure 1)**.

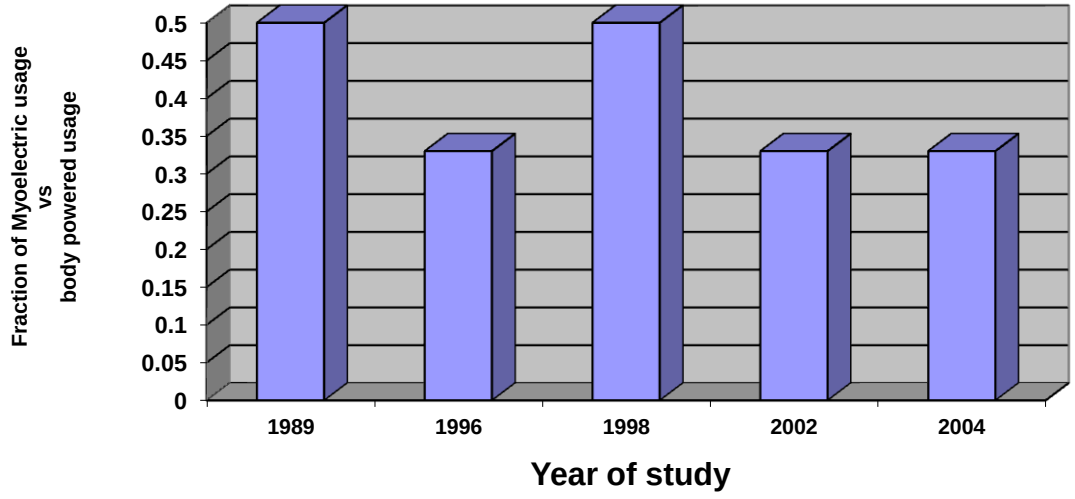


Figure 1: Usage rates of myoelectric prostheses v body-powered prostheses [2, 3, 4, 5, 6]

Despite the many modifications and improvements that have been introduced to myoelectric systems and components over this period, the rate of usage for myoelectric prostheses compared to body-powered prostheses has changed little. This suggests an underlying cause unrelated to the technical specifications and features associated with myoelectric systems and components.

One prescription element within the myoelectric prosthesis that has not been altered over the last twenty years is the socket. It is from within the socket, via electrodes located within its structure, that the user must ultimately control the myoelectric prosthesis prehensor. Despite being very similar in design, fitting and application, the body-powered prosthesis socket has no bearing on prosthesis control, as this is achieved via a harness. A key feature of body-powered prostheses is the consistency of control and response available from the harness. The user will always gain a proportional response from the prehensor for an equal amount of effort and movement. Anecdotal evidence from users and clinicians has suggested that this is not the same for myoelectric prostheses, and has also indicated socket influences on myoelectric control and usability, prompting this investigation. If inconsistent responses, linked to socket design and fit, compromise the control and operation of myoelectric prostheses, then this could provide some evidence for the anecdotal user complaints previously mentioned. This could then be a significant factor in the demonstrably low usage rates of myoelectric prostheses.

4. Myoelectric control: why socket fit is important for consistent prehensor response

4.1 The EMG signal and the role of the electrodes

The EMG signal necessary for myoelectric control is generated from residual limb musculature, and is very small in magnitude [7]. A much larger signal, ever present at the skins' surface, is the common mode voltage [8]. The common mode voltage exists as a consequence of the body acting as an antenna for the many electrical signals that constantly surround it. If the much smaller EMG signal is to be measured and used as an operating signal, then this common mode voltage must be filtered out, thus requiring the use of differential electrodes. Unfortunately these rely on an intimate fit over the skin at all times; if one of the diodes lifts off from the skin, then filtering of the common mode voltage is stopped and this then registers as a large signal in its own right, thus activating the prehensor [8]. Thus, if movement

occurs between the socket and the residual limb that is significant enough to lift part of the electrode away from the skin, even momentarily, then the common mode voltage will become an ‘active signal’ and the prehensor will be activated inadvertently. This is precisely what the anecdotal evidence from users has suggested.

4.2 Socket design

People who have limb absences at the transradial level are the most frequent users of upper limb prostheses [9]. Those whose absence occurs more proximally either do not use prostheses at all, or use predominantly cosmetic types [9]. For these reasons, only transradial prostheses users will be chosen to participate in this study.

The most common type of prosthetic socket used in myoelectric prostheses at this level is the brim type hybrid. This is self-suspending, meaning that no straps are required, and encloses the bony anatomical landmarks around the elbow, including both radial epicondyles as well as the olecranon. The brim type hybrid socket, and other socket designs similar to it currently in use, was originally conceived around 1960, at least 10 years before the mainstream implementation of myoelectric prostheses [10]. The specific requirements of myoelectric control relating to electrode security and placement would not have been in the design critique of these sockets. In particular, the effects of motion between the residual limb and the socket would not have been a design consideration. If motion occurred between the socket and the skin of the residual limb in the then existing body-powered or cosmetic prostheses, then no adverse effects could be expected for the user of the prosthesis. However, this is obviously not the case for the myoelectric prostheses user, where motion could lead to electrode lift and the inadvertent prehensor responses mentioned previously.

5. The Research question

The evidence stated previously warrants the need for an investigation examining a potential link between socket fit and design, and the low usage rates of myoelectric prostheses. In particular, the research question asks whether motion between the residual limb and the socket affects prosthetic functionality in

myoelectric prostheses. To determine if this is the case, the following assessment methodology is proposed.

6. Assessment methodology

The study uses the questionnaire, see appendix 1, as the research tool for the relevant information on the subject area to be acquired. The questionnaire is split up into four sections:

1) **Section A: A few questions about you**: This section is aimed at providing a basic amount of information about the individual which may help to provide a backdrop for data from the later sections.
2) **Section B: Using your myoelectric prosthesis**. This section investigates usage rates, what activities the prosthesis is used for and whether other types of prosthesis are used in and around the myoelectric prosthesis.
3) **Section C: About your socket**. This section investigates the role that the prosthetic interface or socket plays in the transmission of electrical signals via the electrodes. Its questions are particularly aimed at evaluating the fit of the myoelectric socket for each user, and determining the relationship between this and the activation and operation of the myoelectric terminal device.
4) **Section D: If you rejected your myoelectric prosthesis**. This section is only to be completed by those prosthesis users who have rejected their myoelectric prostheses, and simply enquires as to the reasons that this decision may have been taken. This is in order to identify if there is a link between rejection of the prosthesis and poor functional control, which may in itself be linked to the information gathered form data previously acquired.

The questionnaire is aimed at upper limb myoelectric prosthesis users. As the number of these is relatively small, a few prosthetic service clinics will need to be involved in order to provide the most useful and credible data on the subject area. The following part of this section outlines how this process should be undertaken.

6.1 Distribution Methodology

6.1.1 Prostheses user selection

Prostheses users will be sleeted from disablement service centres located within the United Kingdom. The maximum number of prostheses users that will be

involved in the study will be 150. The selection procedure is detailed in **figure 2** and will be overseen by John Head, lecturer and Prosthetist, from Salford University.

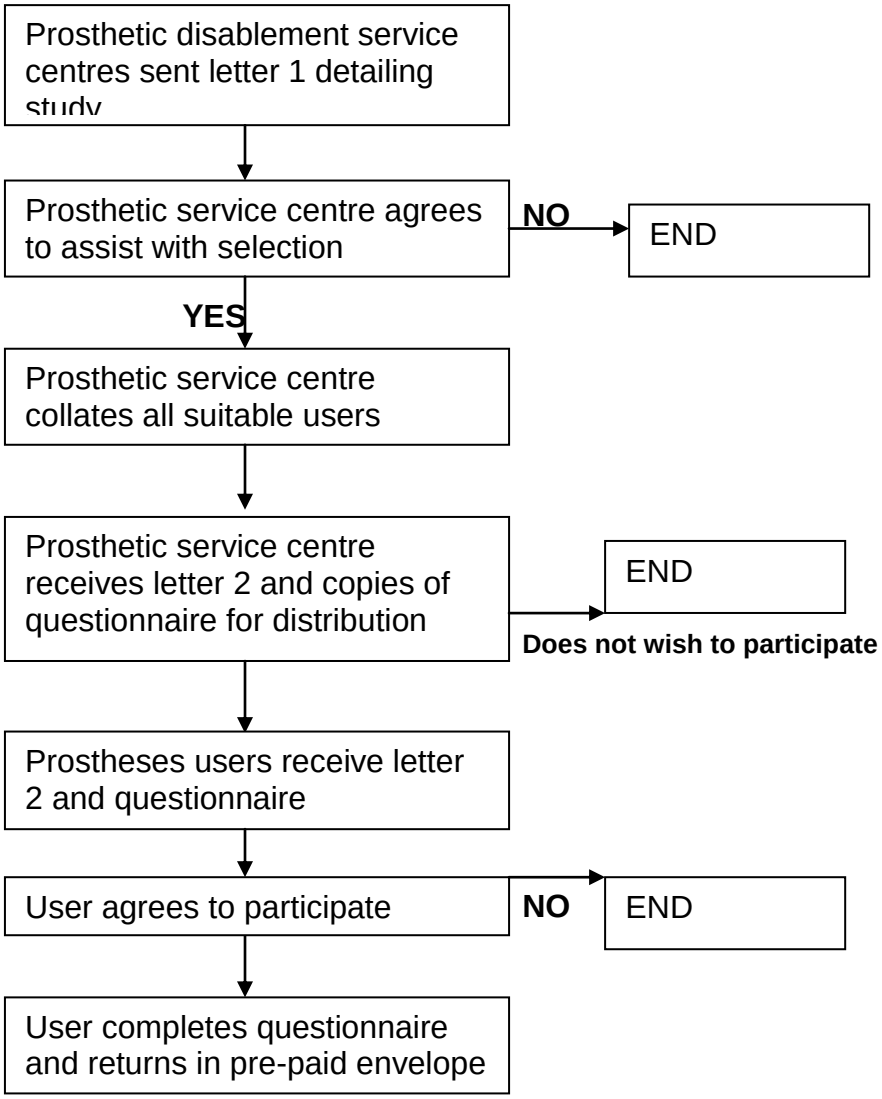


Figure 2: Selection and recruitment procedure

6.1.2 Prostheses user selection criteria

Inclusion criteria

1) A transradial level of limb absence
2) Previous experience using a myoelectric prosthesis
3) Sufficient cognitive ability to follow and complete basic questions necessary for completion of the assessment process.

4) Age over 18.

Prosthetists working at the disablement service centres included in the selection pool will assist in the selection process, and will be provided with a 'subject identification sheet' which outlines the criteria required in accordance with the list given above.

6.2 Data collection

Data will be collected from each user and collated into a central database, which will then be used to investigate the potential links that may be seen to exits between socket fit, usage rate and functionality in myoelectric upper limb prostheses.

7. References

1) http://www.nasdab.co.uk/publications.asp

2) Roeschlein RA, Domholdtz E, Factors related to successful upper extremity prosthetic use. P&O Int, 1989. 13(1): p. 14-8

3) Atkins D, Heard D, Donovan W, Epidemiological overview of individuals with upper limb loss and their reported research priorities. J P&O, 1996. 8(1): p. 2-13.

4) Kyberd PJ, Davey J, Dougall Morrison J, A survey of upper limb prosthesis users in Oxfordshire. J P&O, 1998. 10(4): p. 85-91.

5) Jones LE, A survey of the dissatisfaction of upper limb amputees with their prostheses, their lifestyles and their abilities. J Hand Ther, 2002. 15(1): p. 62-70.

6) Dudkiewicz I, Gabriolov R, Seivner I, Zelig G, Heim M, Evaluation of prosthetic usage in upper limb amputees. Disabil Rehabil, 2004. 26(1): p. 60-3.

7) Bottomly A, Myoelectric control of powered prostheses. J Bone & Joint surg, 1965. 47B(3): p. 411-15.

8) Muzumdar A, Powered Upper Limb Prostheses: Control, Implementation and Clinical Application; 2004; Springer-Verlag, Berlin.

9) Peizer EP, Pirello T, Principles and practice in upper extremity prosthetics. Orth Clin NAm, 1972. 3(2): p. 397-417. 50.

10) Hepp O, Kuhn GG, Upper Extremity Prostheses Prosthetics International, Proceedings of the Second International Prosthetics Course, Copenhagen, Denmark, July 30 to August 8, 1959. Copenhagen: Committee on Prostheses, Braces and Technical Aids, International Society for the Welfare of Cripples, 1960:133–181.

11) Light CM, Chappell P, Kyberd PJ, Establishing a standardised clinical assessment tool of pathologic and prosthetic hand function: normative data, reliability and validity. Arch Phys Med Rehabil, 2002. 83: p. 776-83.

12) http://www.soton.ac.uk/~cdm1/shap.htm

Analysing the relationship between upper limb socket and electrode design and low levels of functionality in myoelectric prostheses: A prosthesis user questionnaire

1. Introduction

This protocol relates to one of a series of investigations designed to assess the efficacy of current prosthetic interface (socket) designs with regard to myoelectric prostheses functionality. Myoelectric prostheses use electromyographic (EMG) signals from residual limb muscles encapsulated within the prosthetic socket to operate electrically powered prehensors. These EMG signals are picked up via electrodes that are housed within the inner wall of the socket. The goal of the work is to ascertain the levels of motion that occur between these electrodes and the residual limb and the extent to which this motion inhibits functional usage and prosthetic functionality. It is hoped that this research may eventually lead to an electrode design that provides optimum contact and improved functionality.

This particular part of the study involves the distribution of a carefully constructed questionnaire to known myoelectric prostheses users, seeking information regarding their prosthesis usage rates, socket types and fit, and any problems with usage that they may have encountered that could be related to electrode contact problems within the socket. The information gathered would be used to construct a data base of responses that could show if a link between socket design, electrode contact and prosthesis usage and functionality exists. This could then be used to supplement other data being gathered around this subject area and ultimately lead to improvements in the provision of prosthesis components and design, leading to greater and more effective functional usage for upper limb myoelectric prosthesis wearers.

2. Scientific background

According to the National Amputee Statistical Database, there were 242 new upper limb amputees and 92 new referrals of upper limb congenital cases between

2005/2006 [1]. The majority of these were at either the transradial or transhumeral levels of limb absence. Most amputations of the upper limb occur due to traumatic

injury. The reasons for congenital limb absence are more complex, and are still not completely understood.

The loss of all or part of an upper limb is extremely detrimental to a person's physical and psychological well-being. The natural upper limb has an excellent command and control structure, an effective and extremely mobile segmented limb, and a highly dextrous manipulator in the form of the hand, which is able to perform numerous tasks promptly and effectively. At present, replacing these elements prosthetically is very difficult to achieve. Current functional alternatives use to control prehensors are either:

3) Body-powered, using a cumbersome harness and biomechanical control, or
4) Myoelectrically operated, using EMG signals generated within residual limb musculature.

The former, although uncosmetic, restrictive and outdated, still remain the most functional type of prosthesis, despite being largely unchanged in design for almost a century [2]. The advantages offered by self-contained, myoelectric prostheses suggest that these should be far more popular than body-powered prostheses. However, survey results have not suggested that this is always the case [3, 4].

3. Myoelectric usage and functionality

There is some debate as to whether a plateau has been reached with respect to myoelectric prosthesis functionality [5]. The fact that there will always be a limited amount of myoelectric signal sites, and therefore a limit to the availability of functions, will inevitably preclude highly complex movements inherently available within the sound hand and arm. Nevertheless, limited movements are also a characteristic of body-powered devices, and yet these prostheses appear to be more effective at reproducing higher levels of functionality [3, 4].

One area of the prosthesis that has received little attention in recent years has been the prosthetic interface, or socket. The socket provides the housing for electrodes that

amplify and relay the myoelectric signal to the processing units located within the myoelectric hand, as well as maintaining a comfortable and secure contact between the residuum and the prosthesis.

Currently, differential electrodes are used to provide the signal recognition capability within modern myoelectric systems. Crucially, differential electrodes rely on continuous and secure contact with the skin to operate effectively. Motion between the electrode and the skin, or a break in contact, may lead to false signal production and unwanted activation of the myoelectric hand [6].

Standard prosthetic sockets are not specifically designed to restrict motion between the residuum and the electrodes, since their original development came about prior to the introduction of clinical myoelectric systems [7].

This preliminary study investigates how the attachment between the electrode and the residual limb may affect prosthesis functionality. One prescription element within the myoelectric prosthesis that has not been altered over the last twenty years is the socket. It is from within the socket, via electrodes located within its structure, that the user must ultimately control the myoelectric prosthesis prehensor. Despite being very similar in design, fitting and application, the body-powered prosthesis socket has no bearing on prosthesis control, as this is achieved via a harness. A key feature of body-powered prostheses is the consistency of control and response available from the harness. The user will always gain a proportional response from the prehensor for an equal amount of effort and movement. Anecdotal evidence from users and clinicians has suggested that this is not the same for myoelectric prostheses, and has also indicated socket influences on myoelectric control and usability, prompting this investigation. If inconsistent responses, linked to socket design and fit, compromise the control and operation of myoelectric prostheses, then this could provide some evidence for the anecdotal user complaints previously mentioned. This could then be a significant factor in the demonstrably low usage rates of myoelectric prostheses.

4. Myoelectric control: why socket fit is important for consistent prehensor response

4.1 The EMG signal and the role of the electrodes

The EMG signal necessary for myoelectric control is generated from residual limb musculature, and is very small in magnitude [8]. A much larger signal, ever present at the skins' surface, is the common mode voltage [9]. The common mode voltage exists as a consequence of the body acting as an antenna for the many electrical signals that constantly surround it. If the much smaller EMG signal is to be

measured and used as an operating signal, then this common mode voltage must be filtered out, thus requiring the use of differential electrodes. Unfortunately these rely on an intimate fit over the skin at all times; if one of the diodes lifts off from the skin, then filtering of the common mode voltage is stopped and this then registers as a large signal in its own right, thus activating the prehensor [9]. Thus, if movement occurs between the socket and the residual limb that is significant enough to lift part of the electrode away from the skin, even momentarily, then the common mode voltage will become an 'active signal' and the prehensor will be activated inadvertently. This is precisely what the anecdotal evidence from users has suggested.

4.2 Socket design

The specific requirements of myoelectric control relating to electrode security and placement would not have been in the design critique of most upper limb sockets. In particular, the effects of motion between the residual limb and the socket would not have been a design consideration. If motion occurred between the socket and the skin of the residual limb in the then existing body-powered or cosmetic prostheses, then no adverse effects could be expected for the user of the prosthesis. However, this is obviously not the case for the myoelectric prostheses user, where motion could lead to electrode lift and the inadvertent prehensor responses mentioned previously.

Most upper limb myoelectric prosthesis users have a limb absence at the transradial level. Those whose absence occurs more proximally tend not to use functional

prostheses as frequently [2]. However, all levels will be considered here in view of the relatively low numbers of all myoelectric users.

5. The Research question

The evidence stated previously warrants the need for an investigation examining a potential link between socket fit and design, and the low usage rates of myoelectric prostheses. In particular, the research question asks whether motion between the residual limb and the socket affects prosthetic functionality in

myoelectric prostheses. To determine if this is the case, the following assessment methodology is proposed.

6. Assessment methodology

The study uses the questionnaire (see questionnaire document) as the research tool for the relevant information on the subject area to be acquired. The questionnaire is split up into four sections:

5) **Section A: A few questions about you**: This section is aimed at providing a basic amount of information about the individual which may help to provide a backdrop for data from the later sections.
6) **Section B: Using your myoelectric prosthesis**. This section investigates usage rates, what activities the prosthesis is used for and whether other types of prosthesis are used in and around the myoelectric prosthesis.
7) **Section C:** A**bout your socket**. This section investigates the role that the prosthetic interface or socket plays in the transmission of electrical signals via the

   electrodes. Its questions are particularly aimed at evaluating the fit of the myoelectric socket for each user, and determining the relationship between this and the activation and operation of the myoelectric terminal device.
8) **Section D: If you rejected your myoelectric prosthesis**. This section is only to be completed by those prosthesis users who have rejected their myoelectric prostheses, and simply enquires as to the reasons that this decision may have been taken. This is in order to identify if there is a link between rejection of the

prosthesis and poor functional control, which may in itself be linked to the information gathered from data previously acquired.

The questionnaire is aimed at upper limb myoelectric prosthesis users. As the number of these is relatively small, it is hoped that other prosthetic service clinics as well as Manchester DSC will be involved in order to provide the most useful and credible data on the subject area. The following part of this section outlines how this process should be undertaken.

6.1 Distribution Methodology

6.1.1 Prostheses user selection

Prostheses users will initially be selected from the Manchester area Disablement service centre, Withington Hospital, Manchester. The maximum number of prostheses users that will be involved in the study will be 70. The selection procedure is detailed in **figure 2 (see pg 7)** and will be overseen by John Head, lecturer and Prosthetist, from Salford University.

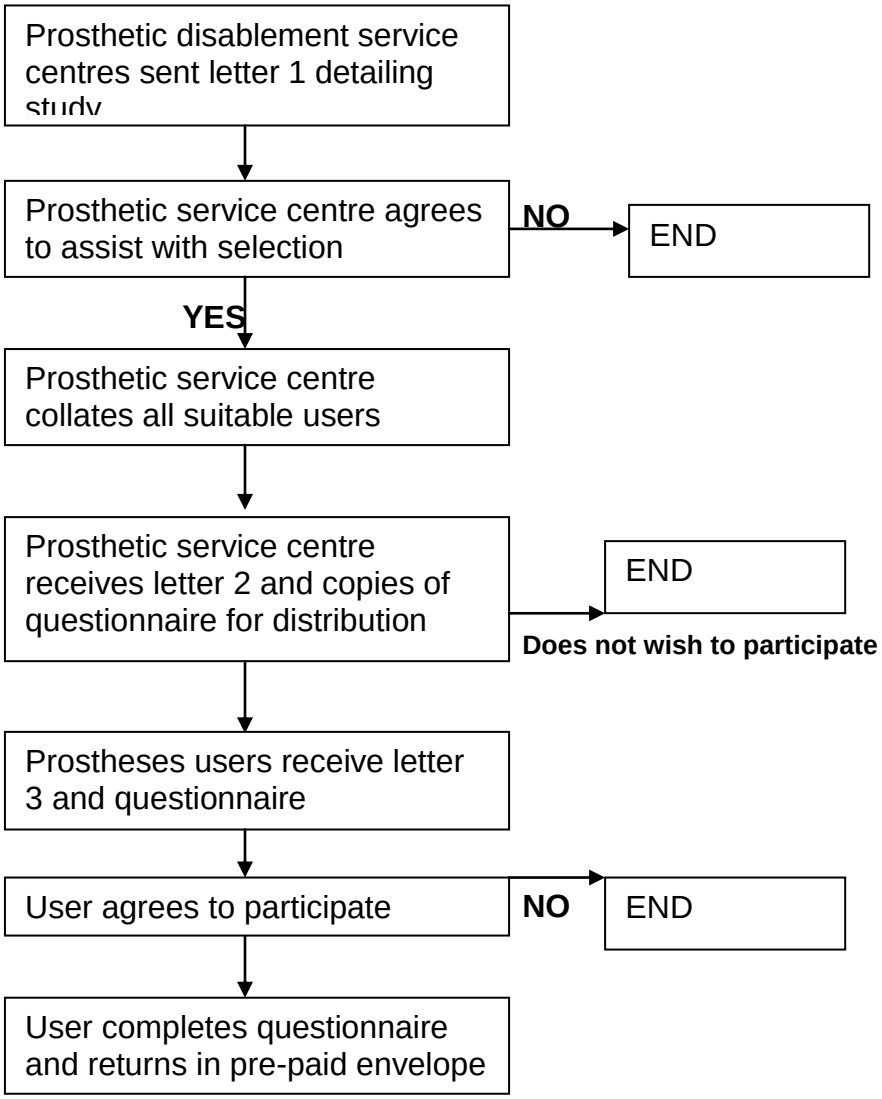


Figure 2: Selection and recruitment procedure

6.1.2 Prostheses user selection criteria

Inclusion criteria

5) An upper limb level of absence

6) Previous experience using a myoelectric prosthesis

7) Sufficient cognitive ability to follow and complete basic questions necessary for completion of the assessment process.

8) Age over 18.

Prosthetists working at the disablement service centres included in the selection pool will assist in the selection process, and will be provided with a 'subject identification sheet' which outlines the criteria required in accordance with the list given above.

6.2 Data collection

Data will be collected from each user and collated into a central database, which will then be used to investigate the potential links that may be seen to exits between socket fit, usage rate and functionality in myoelectric upper limb prostheses.

8. References

1) National Amputee Statistical database [homepage on the internet; cited on September 9 2008]. Available from: http://www.nasdab.co.uk/publications.asp

2) Stein RB, Walley M, Functional comparison of upper extremity amputees using myoelectric and conventional prostheses. Arch Phys Med rehabil; 1983; 64: 243-8.

3) Atkins D, Heard D, Donovan W, Epidemiological overview of individuals with upper limb loss and their reported research priorities. J P&O; 1996; 8(1): 2-13.

4) Dudkiewicz I, Gabriolov R, Seivner I, Zelig G, Heim M, Evaluation of prosthetic usage in upper limb amputees. Disabil Rehabil; 2004; 26(1): 60-3.

5) Lee RE; Reassessing myoelectric control: is it time to look at alternatives? CMAJ; 1987; 126; 467-9

6) Kampas P, The optimal use of myoelectrics.Med. Orth. Tech; 2001; 121: 21-27. Stuttgart

7) Hepp O, Kuhn GG; Upper Extremity Prostheses Prosthetics International, Proceedings of the Second International Prosthetics Course, Copenhagen, Denmark, July 30 to August 8, 1959. Copenhagen: Committee on Prostheses, Braces and Technical Aids, International Society for the Welfare of Cripples, 1960:133–181.

8) Bottomly A, Myoelectric control of powered prostheses. J Bone & Joint surg, 1965. 47B(3): 411-15

9) Muzumdar A, Powered Upper Limb Prostheses: Control, Implementation and Clinical Application; 2004; Springer-Verlag, Berlin.

Appendix A- *emails from academic and professional staff*

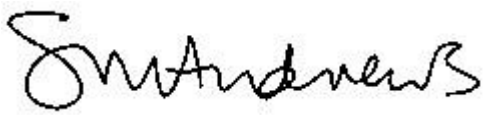
From: Stephen Andrews [mailto:Stephen.Andrews@nbt.nhs.uk]
Sent: 15 April 2008 12:00
To: Head John
Subject: RE: questionnaire

Hello John,

I'm quite happy to send your questionnaire out to our myoelectric users. We do not have many that are full time users, perhaps 5-6. I assume you are excluding children.
The questionnaire seems fine. The only thing that made me stop and think were the phrases "work inside" and "work outside". Would "work indoors" and "work outdoors" be easier to understand?
We have no consultant here so that won't be a problem.

Look forward to hearing from you later.

Kind regards
Steve



Stephen Andrews B.Sc.,Ph.D., SRPros MBAPO
Clinical Manager, Prosthetics
Disablement Services Centre
North Bristol NHS Trust
Tel: 0117 9595736
Fax: 0117 9595730
e-mail: stephen.andrews@nbt.nhs.uk

Comments in track changes - see attached

-----Original Message-----
From: Head John
Sent: Wed 31/01/2007 16:24
To: Hogg Peter
Subject: questionnaire

Hi Peter,
Here is my draft questionnaire. Your comments would be most welcome.

Cheers

John <<A Questionnaire on Myoelectric prosthese12.doc>>

From: Head John
Sent: 10 January 2008 12:10
To: nickhillsdon@hotmail.co.uk
Subject: questionnaire
Attachments: Questionnaire doc..doc

Hi Nick,
Thank you for agreeing to have a look at my questionnaire, which will be used as part of an investigation evaluating electrode contact scenarios, and the resultant levels of prosthesis functionality. The long term aim is to try to develop improvements in electrode designs and implementations within the socket. Feel free to add your comments where appropriate, or via email return.

Thanks once again for your help. I will be writing to the centre consultants shortly in the hope that they will agree to the questionnaire being sent to patients within their centres. If you have any ideas that may help with the distribution please let me know. If you are really helpful, I will put your name on the paper once it is published!
Cheers

John

Appendix B-*Ethical processes and procedures: ethical approval documents*

NHS

National Research Ethics Service

Oldham Local Research Ethics Committee
Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2336
Fax: 0161 237 2383

23 August 2007

Mr John S Head
Lecturer
Frederick Road
Salford
Manchester
M6 6PU

Dear Mr Head

Study title: **An analysis of the relationship between socket design and functionality in myoelectric prostheses**
REC reference: **06/Q1405/73**
Amendment number:
Amendment date:

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 09 August 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire		
Protocol		
Notice of Substantial Amendment (non-CTIMPs)		
Letter of invitation to participant		

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

NHS

National Research Ethics Service

Oldham Local Research Ethics Committee

Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2336
Fax: 0161 237 2383

23 August 2007

Mr John S Head
Lecturer
Frederick Road
Salford
Manchester
M6 6PU

Dear Mr Head

Study title: **An analysis of the relationship between socket design and functionality in myoelectric prostheses**

REC reference: **06/Q1405/73**

Amendment number:

Amendment date:

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 09 August 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire		
Protocol		
Notice of Substantial Amendment (non-CTIMPs)		
Letter of invitation to participant		

Investigator CV	Head	
Protocol	1	24 September 2006
Letter from Sponsor		
Letter of invitation to participant	1	24 September 2006
Participant Information Sheet	2	25 October 2006
Participant Consent Form	1	24 September 2006
Response to Request for Further Information	2	25 October 2006
Subject Identification Sheet	1	24 September 2006
Letter re indemnity		
	1	24 September 2006
		01 August 2006

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1405/73	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

pp

Dr Peter Stanley Klimiuk
Chair

Email: carol.ebenezer@northwest.nhs.uk

Enclosures: *Standard approval conditions*

Copy to: Dr M Pilotti

NHS

National Research Ethics Service

Oldham Local Research Ethics Committee

Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2336
Fax: 0161 237 2383

08 February 2008

Mr John S Head, Lecturer
Brian Blatchford Building
University of Salford
Frederick Road
Manchester
M6 6PU

Dear Mr Head

Study title: **An analysis of the relationship between socket design and functionality in myoelectric prostheses**

REC reference: **06/Q1405/73**

Thank you for sending the progress report for the above study dated 06 February 2008. The report will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

The favourable ethical opinion for the study continues to apply for the duration of the research.

06/Q1405/73:	**Please quote this number on all correspondence**

Yours sincerely

Mrs Carol Ebenezer
Committee Co-ordinator

E-mail: carol.ebenezer@northwest.nhs.uk

Copy to: *Dr M Pilotti*

National Research Ethics Service
Oldham Local Research Ethics Committee

Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2336
Fax: 0161 237 2383

08 May 2008

Mr John S Head
Lecturer
Brian Blatchford Building
Frederick Road Campus
University of Salford
Salford
M6 6PU

Dear Mr Head

Study title:	**An analysis of the relationship between socket design and functionality in myoelectric prostheses**
REC reference:	**06/Q1405/73**
Amendment number:	**2**
Amendment date:	**05 May 2008**

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 08 May 2008.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire	1	05 May 2008
Protocol	3	05 May 2008
Prosthetic Centre letter 2	1	05 May 2008
Prosthetic Centre letter 1	1	05 May 2008
Notice of Substantial Amendment (non-CTIMPs)		05 May 2008
Letter of invitation to participant		05 May 2008

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1405/73:	Please quote this number on all correspondence

Yours sincerely

pp

Mrs Carol Ebenezer
Committee Co-ordinator

E-mail: carol.ebenezer@northwest.nhs.uk

Enclosures — List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: *Max Pilotti*

NHS

National Research Ethics Service

North West 10 Research Ethics Committee – GM North
Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP
Tel: 0161 237 2051
Fax: 0161 237 2383
Email: diane.catterall@northwest.nhs.uk

Private & Confidential
Mr J Head
Brian Blatchford Building
Frederick Road Campus
University of Salford
Salford
M6 6PU

09 October 2009

Dear Mr Head

Study title:	**An analysis of the relationship between socket design and functionality in myoelectric prostheses**
REC reference:	**06/Q1405/73**
Amendment number:	**4**
Amendment date:	**29 September 2009**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation. One of the members made a suggestion regarding the patient information sheet, under the heading 'What if something goes wrong': to insert specific name/s and number/s for the participants to contact should they wish to complain. Please provide revised copies with new version numbers and dates should you amend any of the documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Disablement Service Centre letter	3	29 September 2009
Letter of invitation to participant	3	29 September 2009
Participant Consent Form	2	29 September 2009
Participant Information Sheet	2	29 September 2009
Protocol	1	29 September 2009
Notice of Substantial Amendment (non-CTIMPs)	4	29 September 2009

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1405/73:	Please quote this number on all correspondence

Yours sincerely

Mrs Carol Ebenezer
Committee Co-ordinator

E-mail: carol.ebenezer@northwest.nhs.uk

Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1405/73:	Please quote this number on all correspondence

Yours sincerely

Mrs Carol Ebenezer
Committee Co-ordinator

E-mail: carol.ebenezer@northwest.nhs.uk

Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: *University of Salford*

NHS
National Research Ethics Service
NORTH WEST 10 RESEARCH ETHICS COMMITTEE – GREATER MANCHESTER NORTH
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ
Tel: 0161 625 7817
Email: cynthia.carter@northwest.nhs.uk

Mr John Head
Senior Lecturer in Prosthetics & Orthotics
University of Salford
Brian Blatchford Building
Frederick Road Campus
M6 6PU

25 May 2010

Dear Mr Head

Study title:	**An analysis of the relationship between socket design and functionality in myoelectric prostheses**
REC reference:	**06/Q1405/73**
Protocol number:	
Amendment number:	**5**
Amendment date:	**16 April 2010**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

Favourable Opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Acknowledgement/aletter to partcipants	3	16 April 2010
GP/Consultant Information Sheets	3	16 April 2010
Letter of invitation to participant	2	16 April 2010
Protocol	5	16 April 2010
Notice of Substantial Amendment (non-CTIMPs)	5	16 April 2010
Questionnaire: Myoelectric prostheses	3	16 April 2010

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1405/73:	Please quote this number on all correspondence

Yours sincerely

C. Carter

Ms Cynthia Carter
Committee Co-ordinator

Enclosures: List of names and professions of members who took part in the review

Copy to: Tim Clements, Enterprise & Development, University of Salford

Andrew Maines, R&D office for UHSM NHS Foundation Trust

North West 10 Research Ethics Committee - Greater Manchester North

Attendance at Sub-Committee of the REC meeting on 24 May 2010

Name	*Profession*	*Capacity*
Mr Ken Cook	Clinical Services Manager	Expert
Dr Peter Stanley Klimiuk	Consultant Rheumatologist	Expert

Appendix B-***Ethical processes and procedures: University of Salford ethical approval***

Research Committee

Research Governance and Ethics Sub-Committee (RGEC)

MEMORANDU

To **John Head**

cc: Professor Steven Shardlow, Dr Laurence Kenney & Dr Glynn Heath

From M Pilotti, Contracts Officer

Date **05 October 2007**

Subject: **Approval of your Project by RGEC**

Project Title: **Socket effects on myoelectric prostheses functionality**

RGEC Project code: **RGEC06/12**

Following your responses to the committee's queries, based on the information you provided, I can confirm that they have no objections on ethical grounds to your project.

If there are any changes to the project and/or its methodology, please inform the committee as soon as possible.

Regards,

Max Pilotti
Contracts Officer
MP/JG

Appendix B-*Ethical processes and procedures: patient consent form*

Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Analysing the relationship between socket design and low levels of usage and functionality in myoelectric prostheses

Name of Researcher:

John Head, BSc (Hons), Directorate of Prosthetics and Orthotics, University of Salford, Salford, M6 6PU. Tel: 0161 295 2303. E-mail: J.Head@salford.ac.uk

1. I confirm that I have read and understood the **Patient Information Sheet** dated…… (version…..) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Salford University or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

| --- | --- | --- |
Name of Patient	Date	Signature
Name of Person Taking Consent (if different from Researcher)	Date	Signature
Name of Researcher	Date	Signature

Myoelectric signal testing procedure

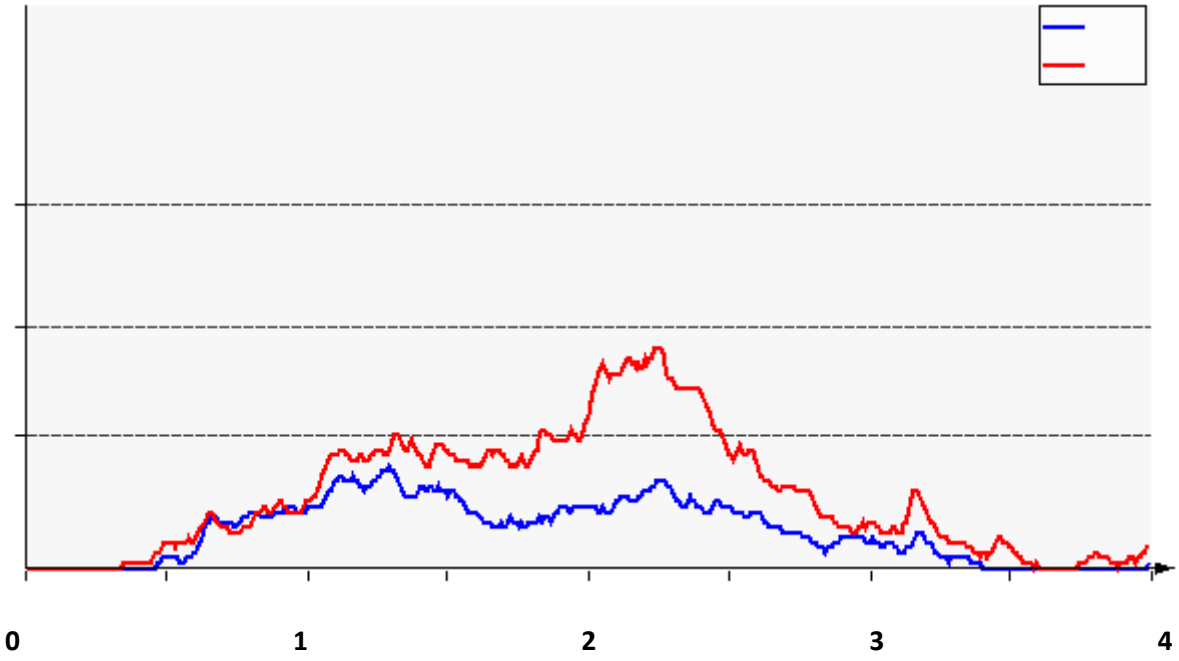
1) Ensure that the testing apparatus is working properly (try it on yourself).
2) Carefully explain the process to the patient. Always try to keep the patient informed about what you are doing and its necessity.
3) Ask the patient to practice flexing and extending the musculature for the relevant sites on the sound side.
4) Choose the apex of the muscle bulk and test for the signal at this point. Then adopt a new position either medially or laterally by~1.5cm and re-test the signal. If it is stronger, then continue in this direction until a maximum is reached. Otherwise go back to the original position and then move in the other direction. Repeat this in the proximal/distal plane until a maximum site strength is achieved, and for a second site if required.
5) Make sure that a reference electrode is used-this is best placed in the sound hand during the testing procedure.
6) Once the optimum site is found, mark this using an indelible crayon.
7) Check that the signal is strong enough to operate a prosthesis, and that the difference is large enough for functional control to be achieved.
8) Make sure that the patient has adequate time between testing so as to give the muscle time to recover
9) Always remember to turn off the tester when finished!

Lamination- Guidelines for myoelectric transradial sockets

1) Make a small stockinet ‘wick’ that will stretch from the base of the cast to just over the first vacuum hole. This wick aids suction.
2) Place a PVA sheet in a wet towel. The sheet must be large enough to stretch over the cast and be tied off just below the 1st vacuum hole. (seek help if necessary)
3) Leave the PVA sheet in the towel for ~10mins. Then, with the help of a colleague, stretch the now pliable sheet over the cast and liner. Tie off the sheet just below the 1st vacuum hole. Cut off any excess PVA.
4) Attach the electrode ‘dummy’ housings to the cast for those sockets requiring these.
5) Next, prepare 6 lengths of stockinet. These must be greater than the length from the top of the cast to below the 2nd vacuum hole.
6) Stretch the lengths of stockinet over the cast, pulling the stockinet down until it just goes beyond the 2nd vacuum hole,.
7) Place a PVA bag in a wet towel.
8) Leave the PVA sheet in the towel for ~10mins. Then, with the help of a colleague, stretch the now pliable bag over the cast/stockinet.
9) Tie off the end of the bag below the stockinet. This must be in firm contact with the post when tied. If necessary cut off excess stockinette before applying the PVA bag. Fold over the top end of the PVA bag, to allow for easier pouring of the resin. Make sure that this can be attached to one of the bulldog clips hanging from the ceiling.
10) Mix ~200gresin as per instructions.
11) Pour the resin into the top of the PVA bag, and attach to bulldog clip.
12) Start easing the resin down by squeezing the pool of resin downwards over the cast. Continue this process over the cast using pre-cut strings of stockinet. Do not allow resin to go beyond the cast.
13) Leave to set.

Appendix D- *results of motion artifacts and movement analysis: signals acquired during the 'Reach' activity for each subject*

Reach activity-No load



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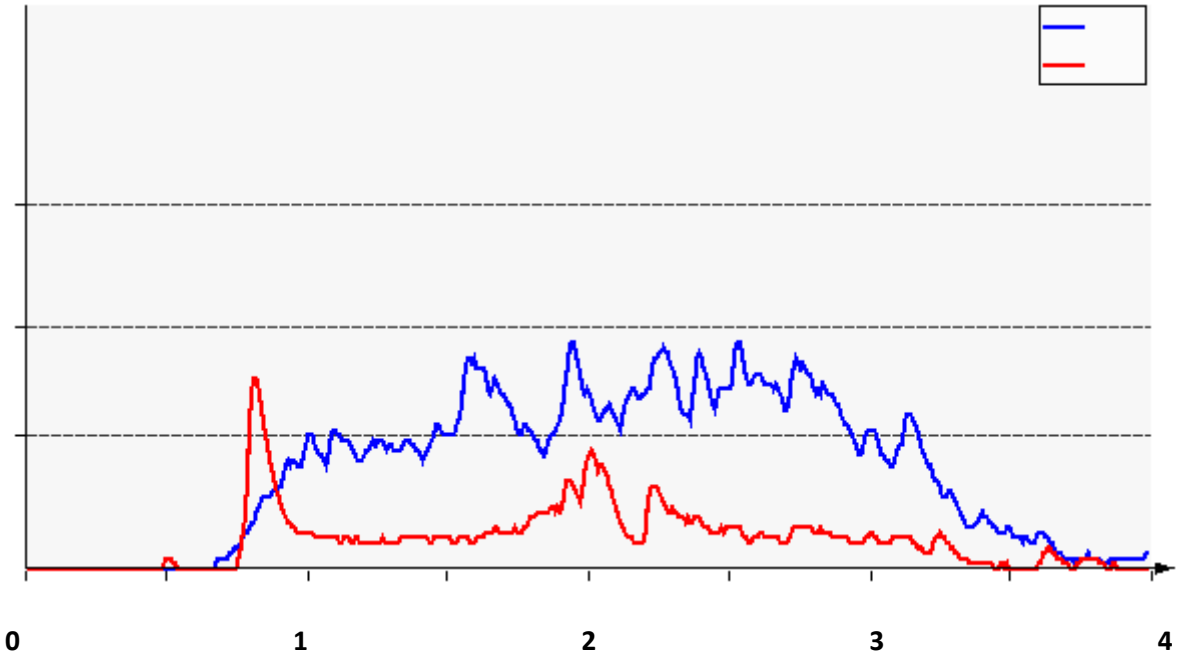

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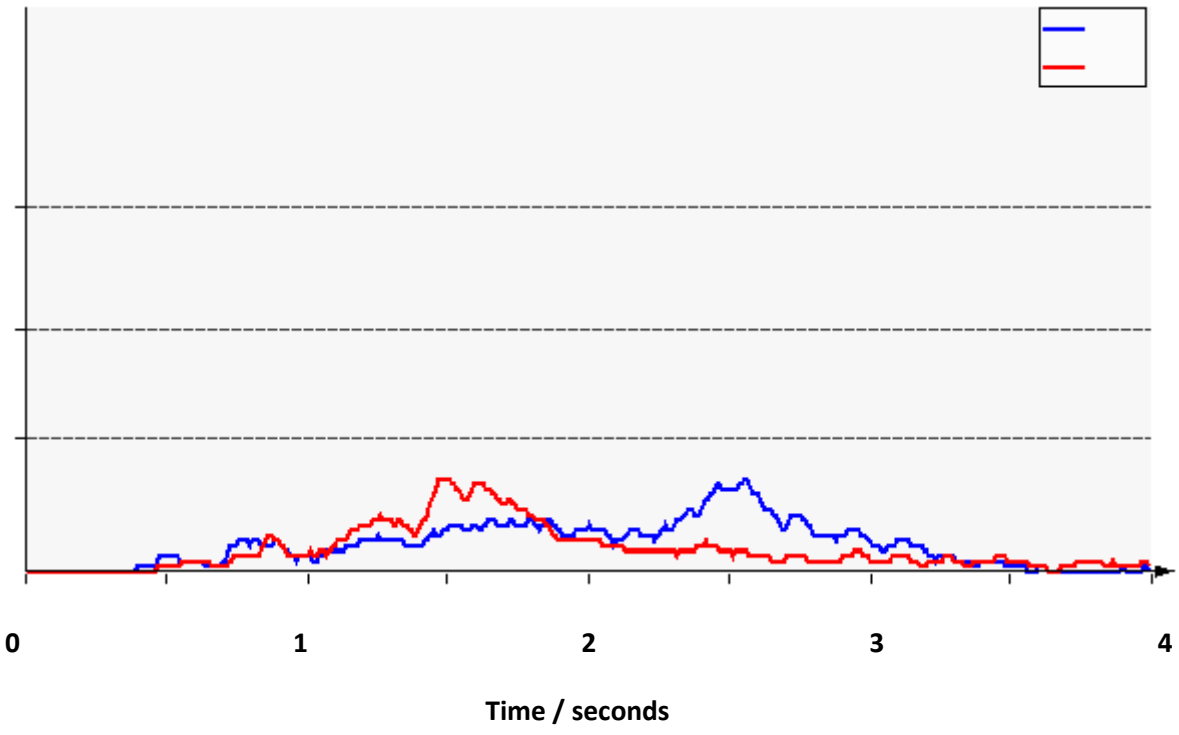

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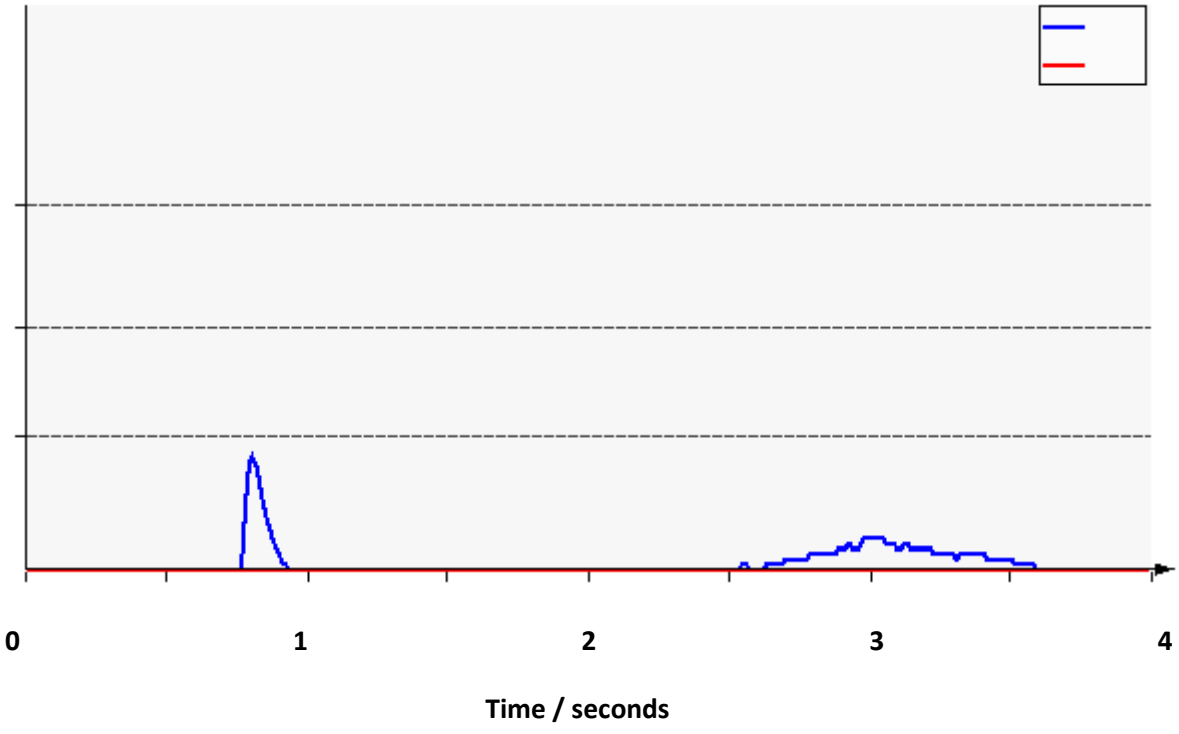
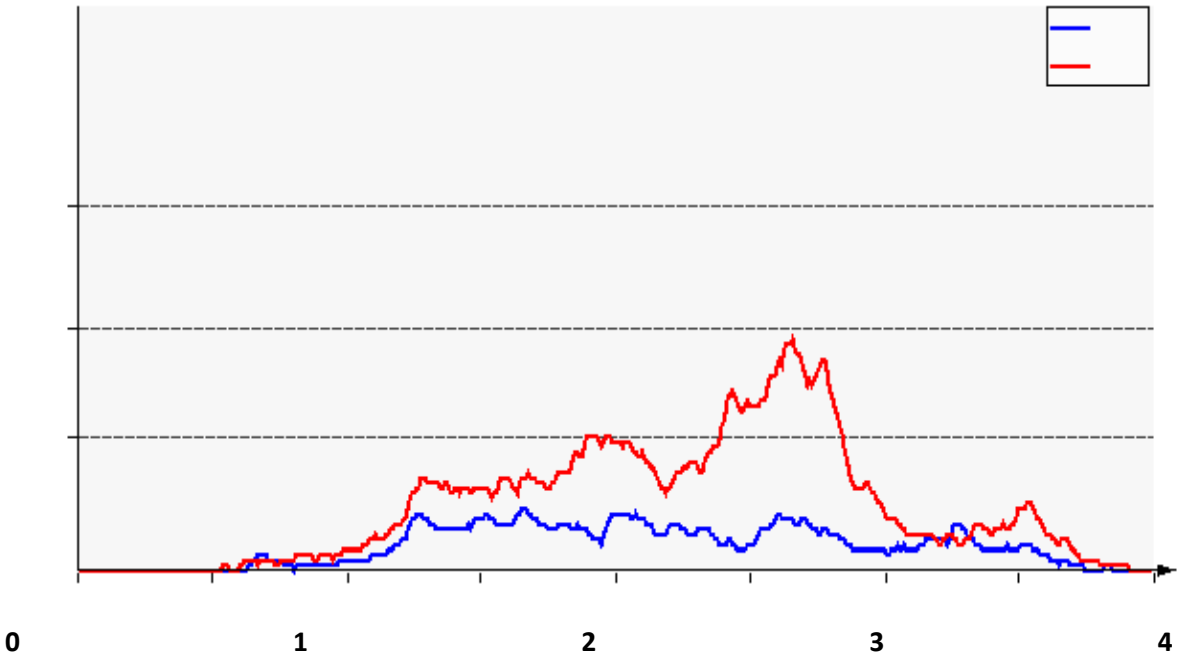


Subject E

Reach activity- 500g



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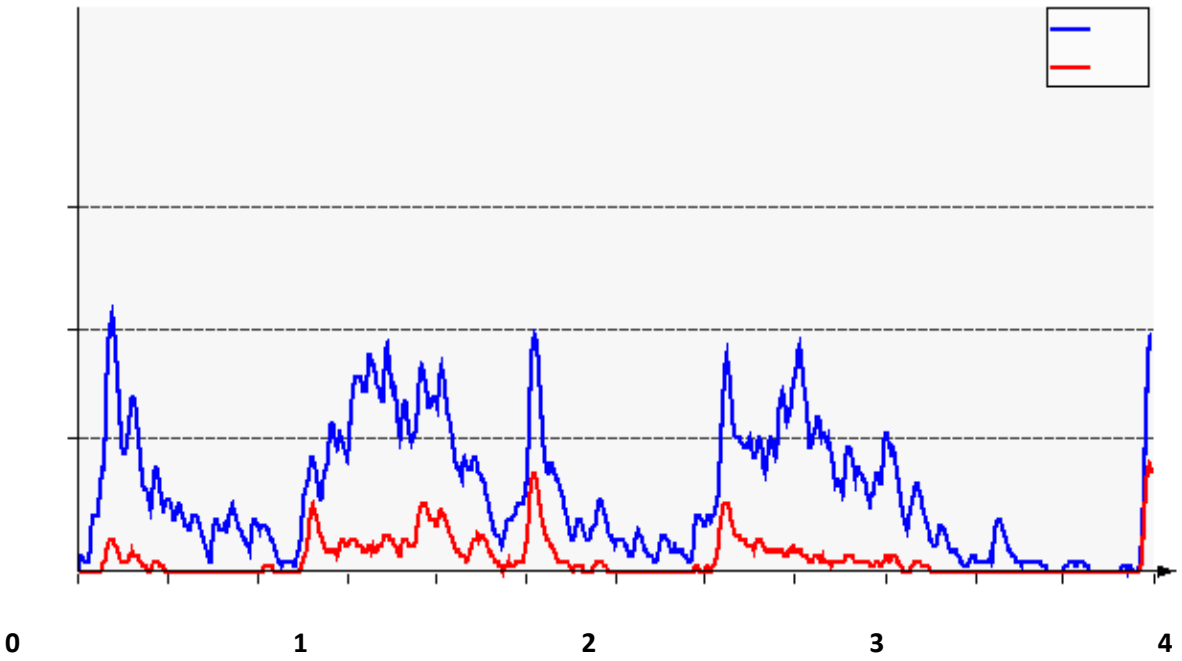

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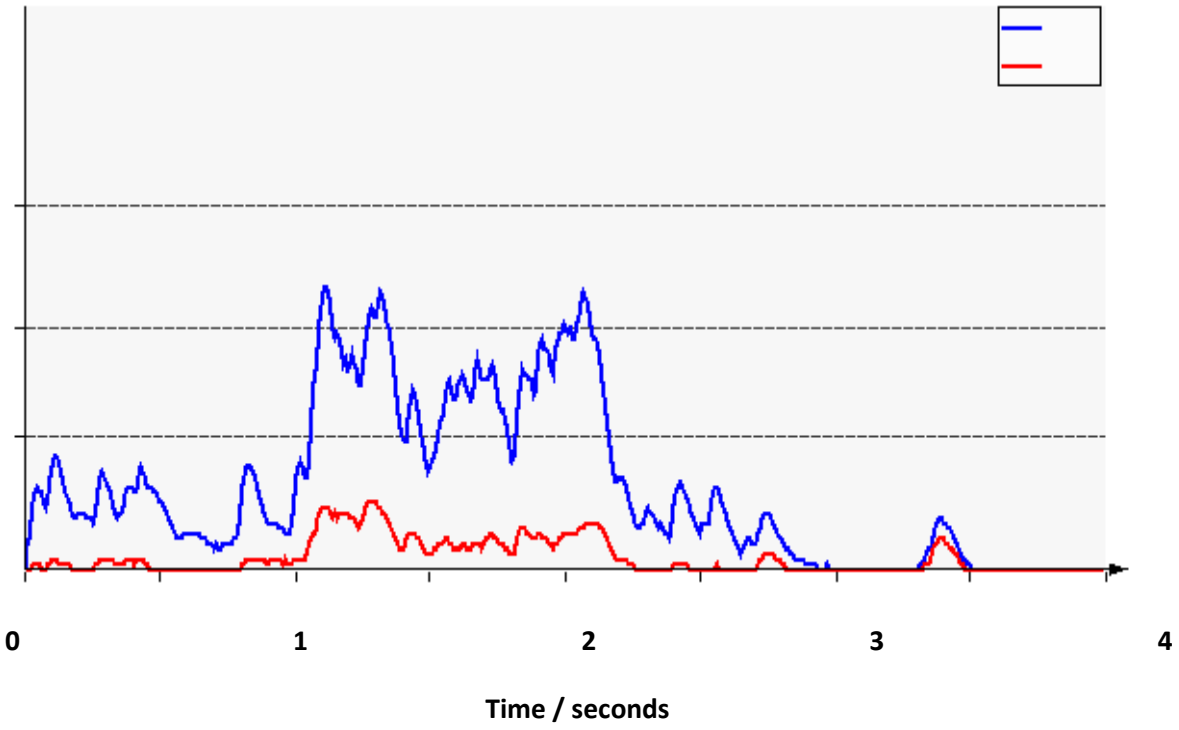

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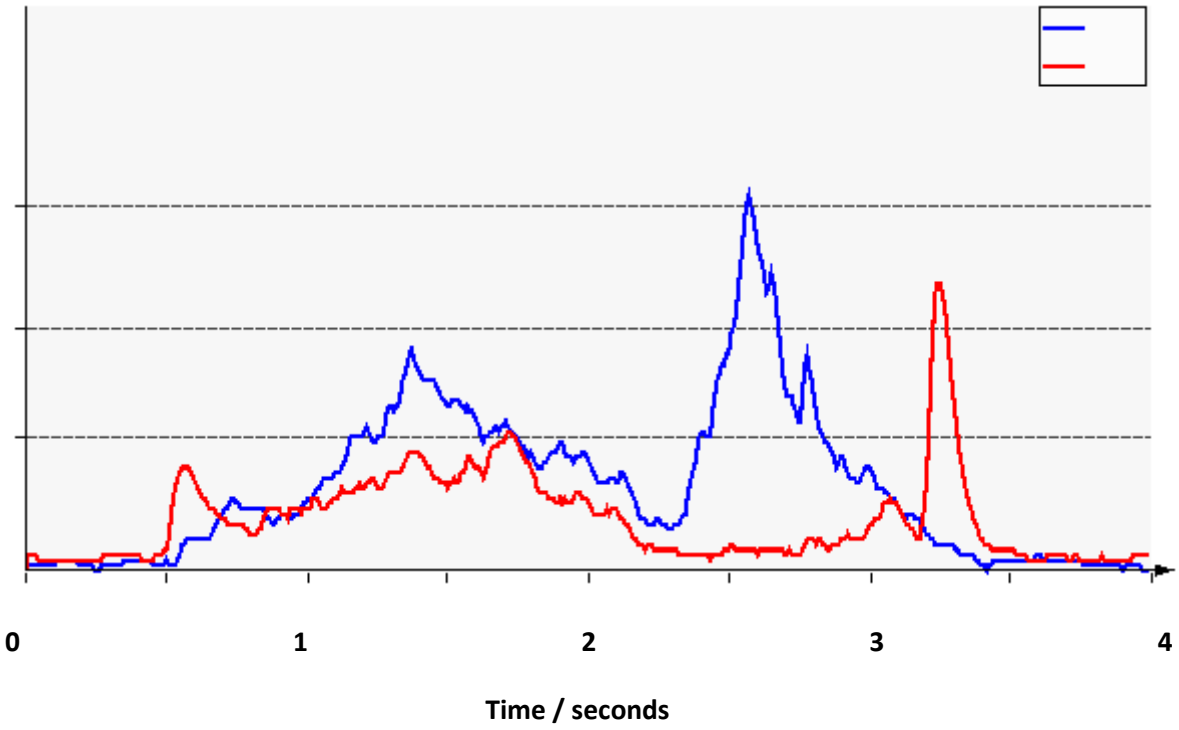

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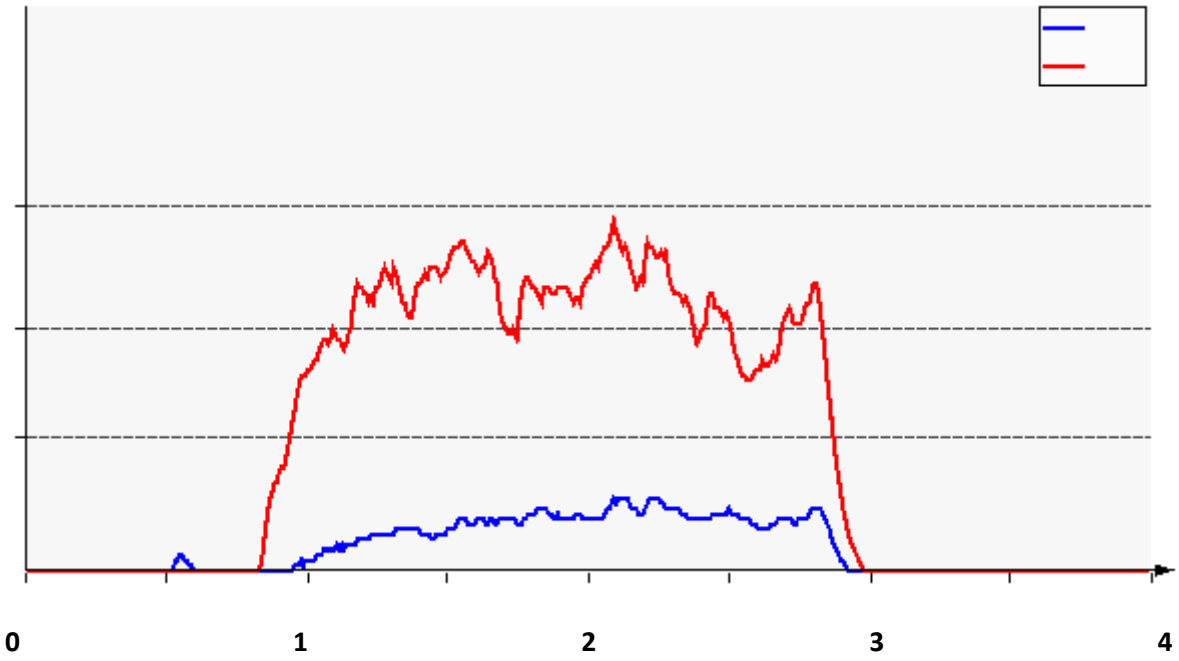

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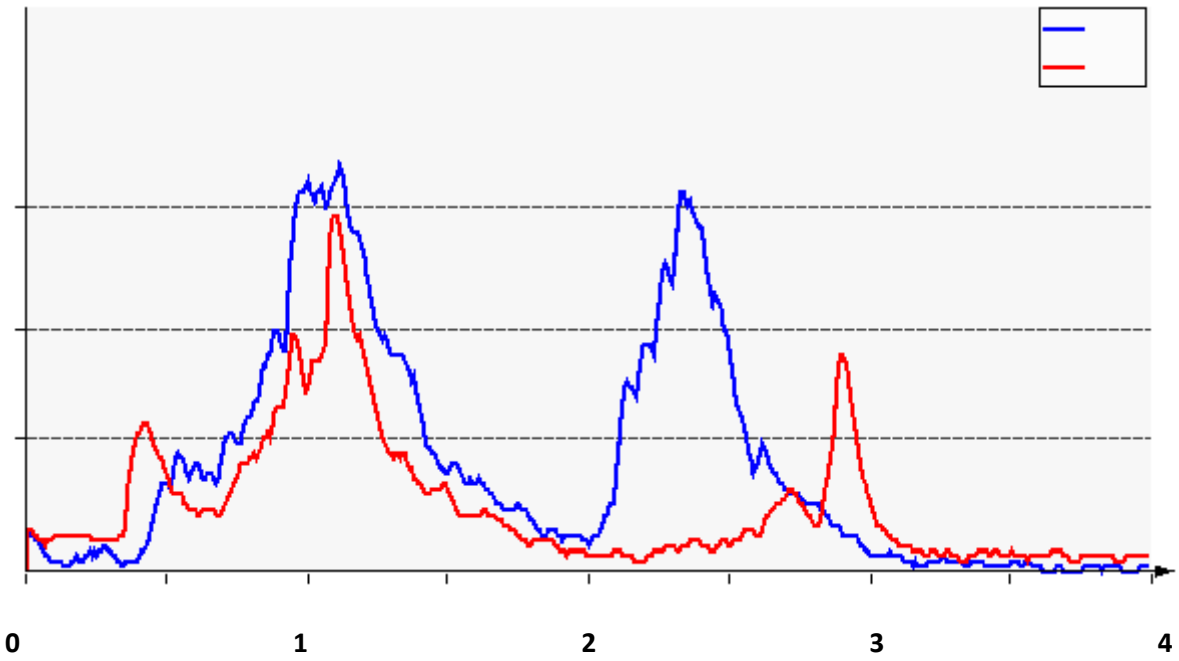

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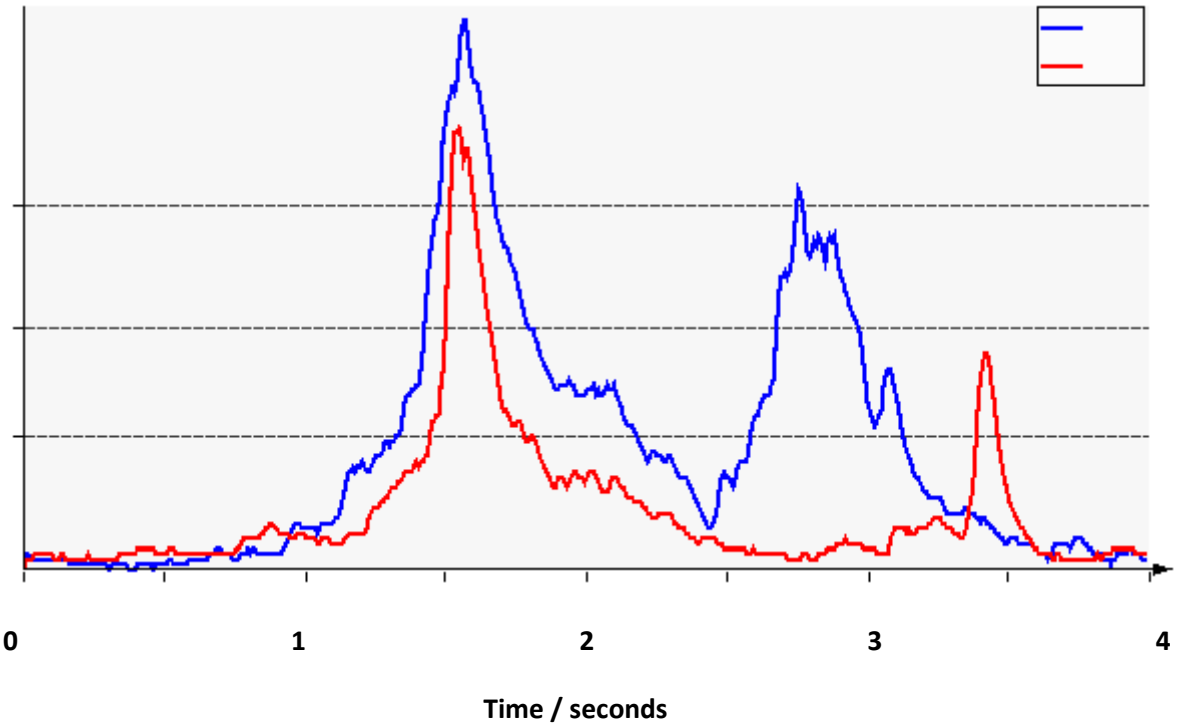

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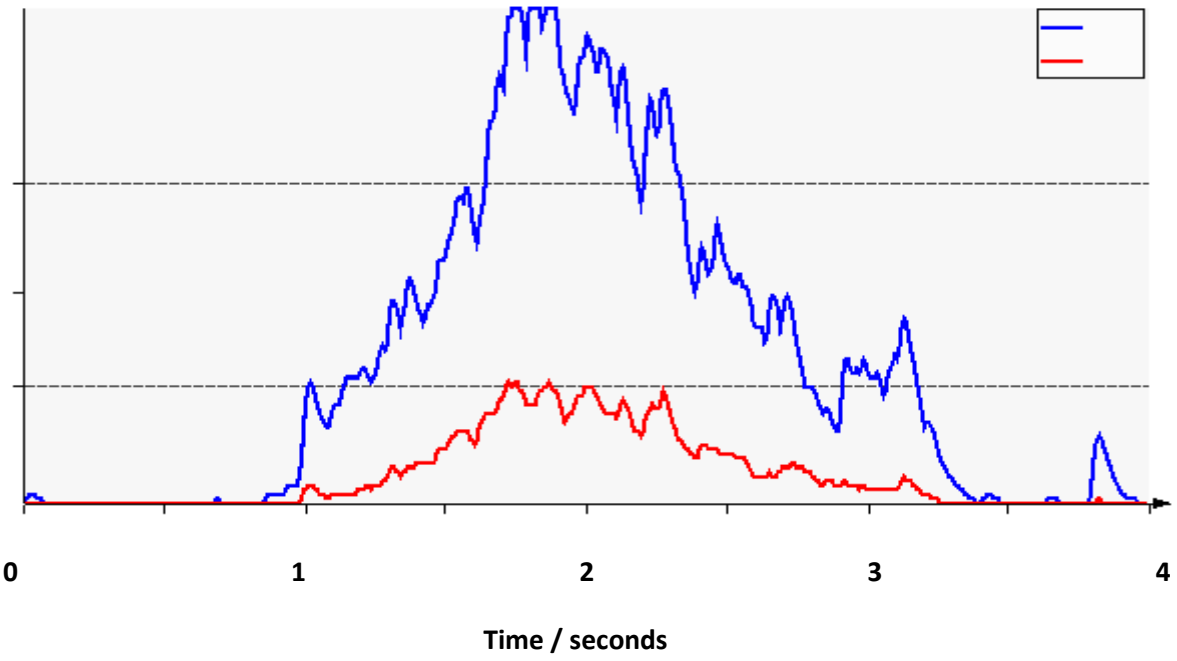
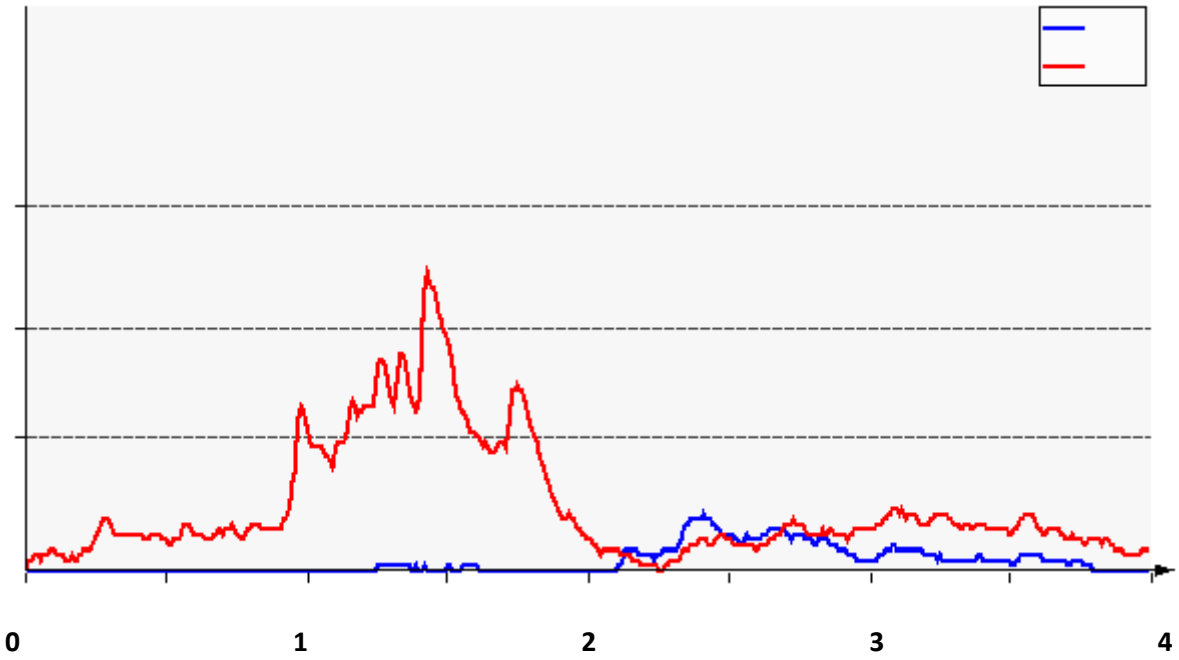


Subject E

Appendix D- *results of motion artifacts and movement analysis: signals acquired during the 'Hand to shoulder' activity for each subject*

Hand to shoulder activity-no load



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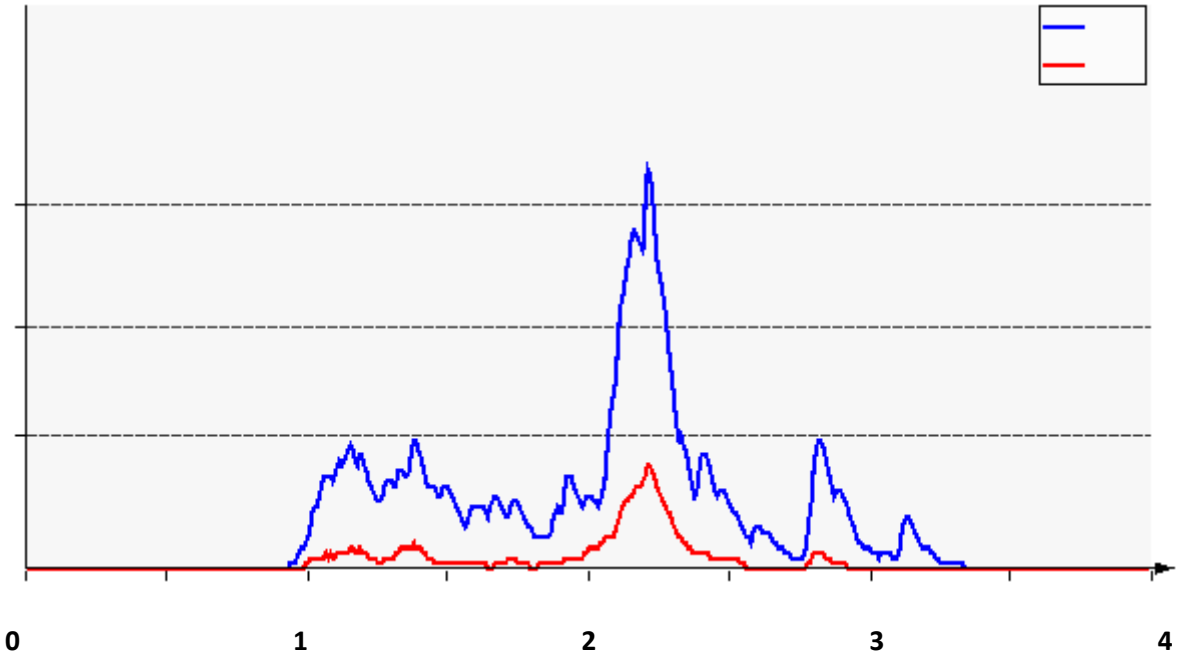

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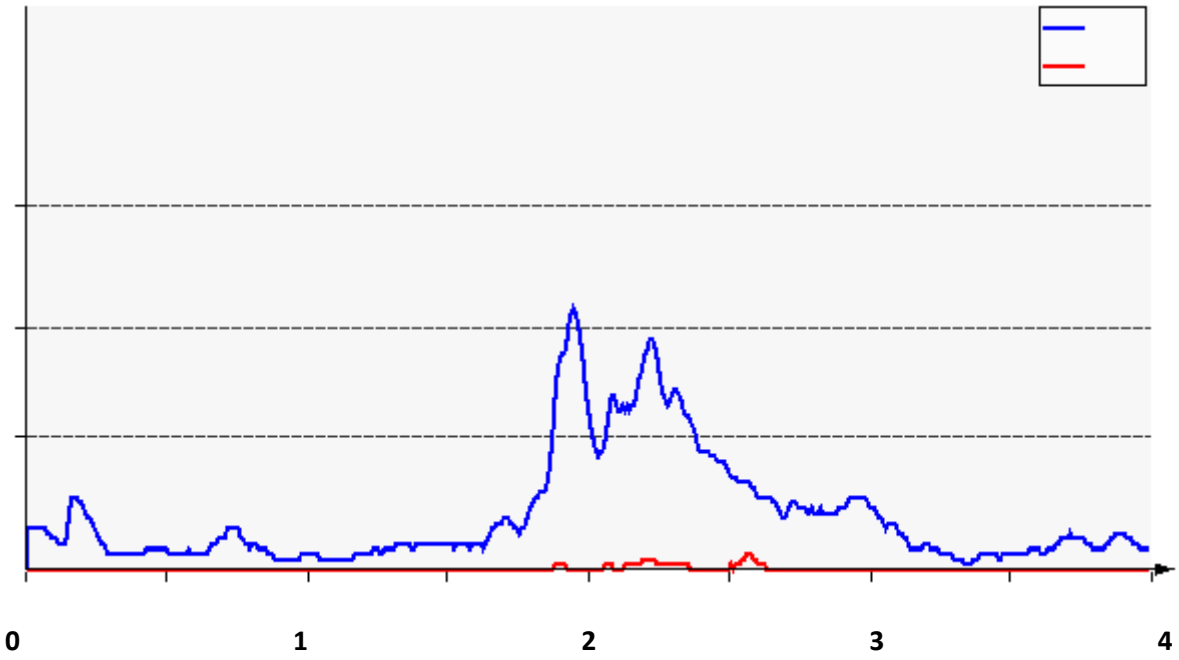

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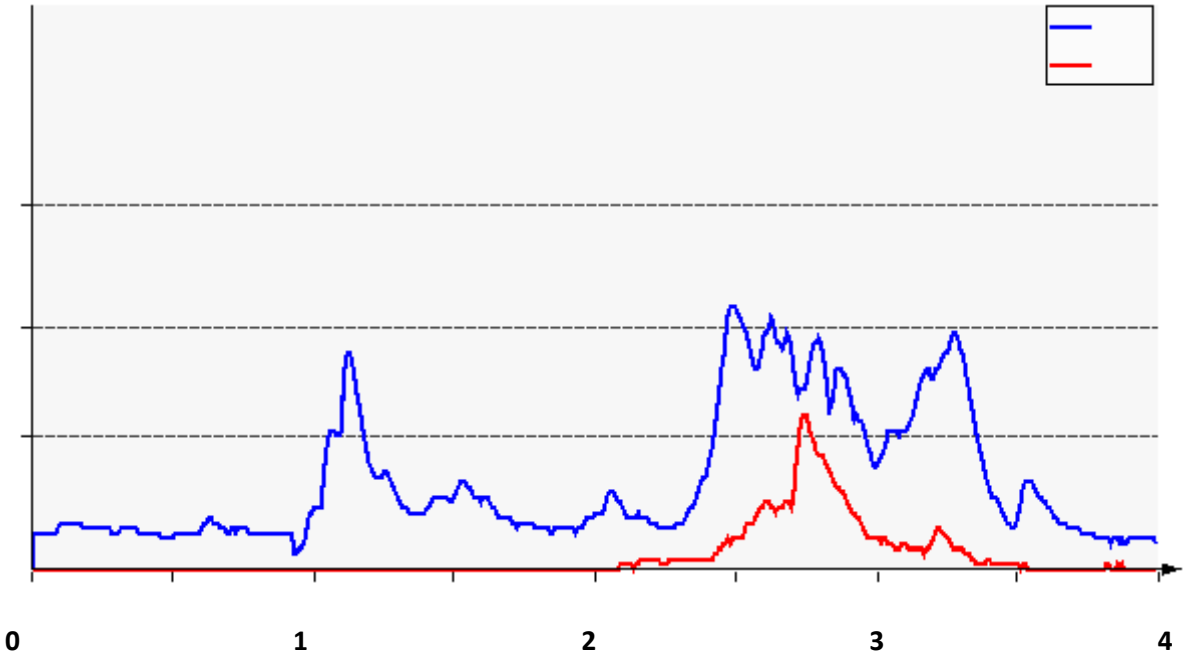

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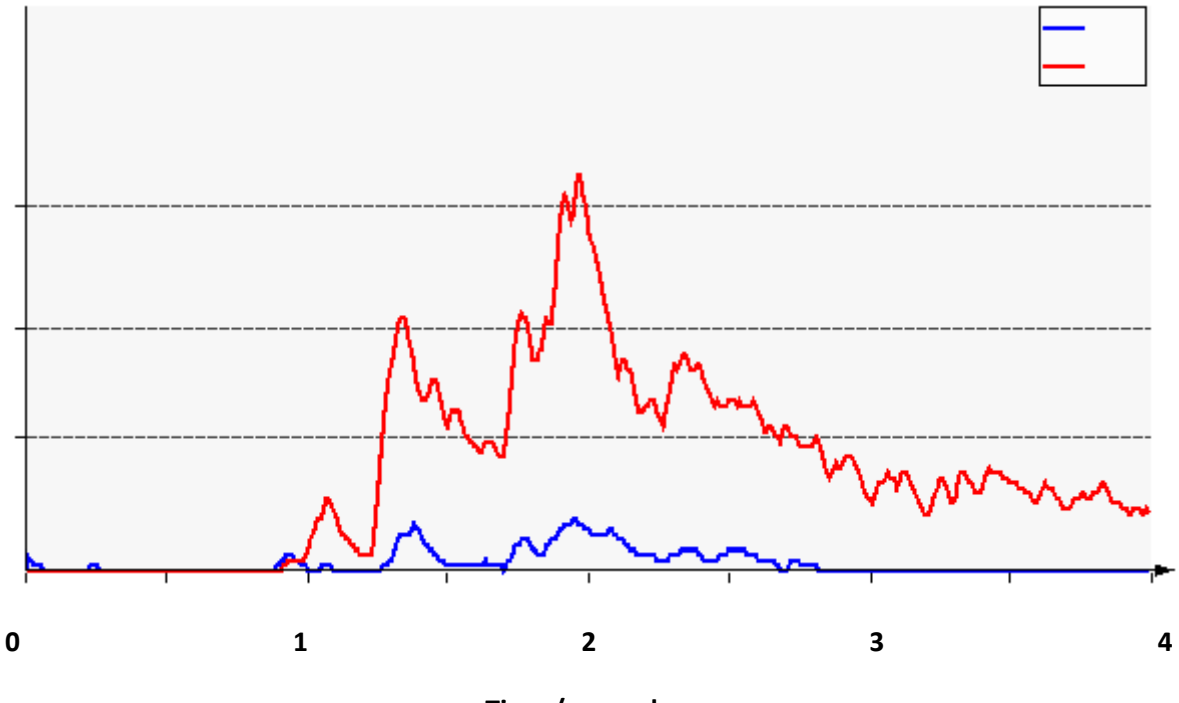
Hand to shoulder activity-500g



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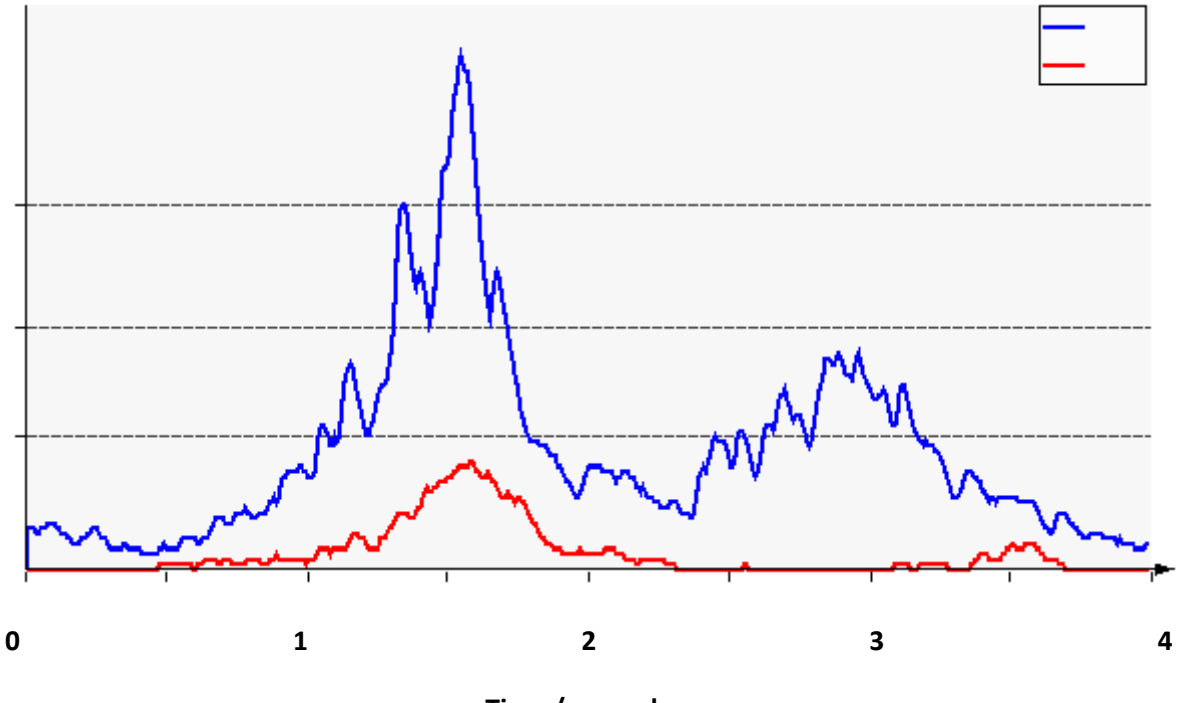

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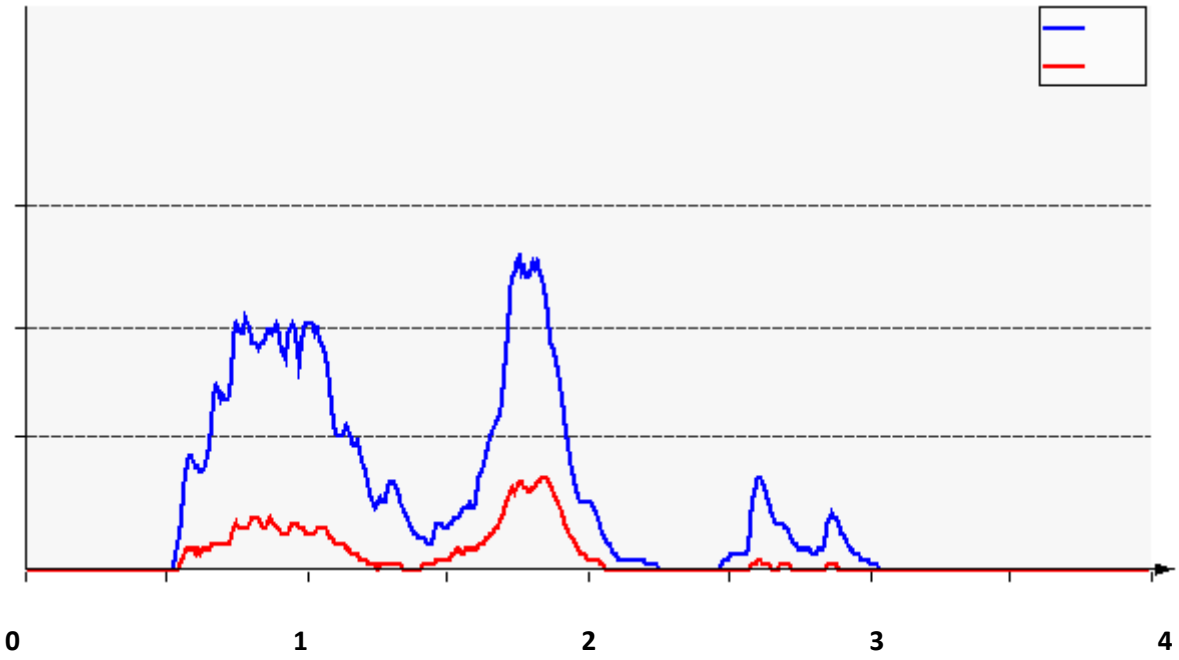

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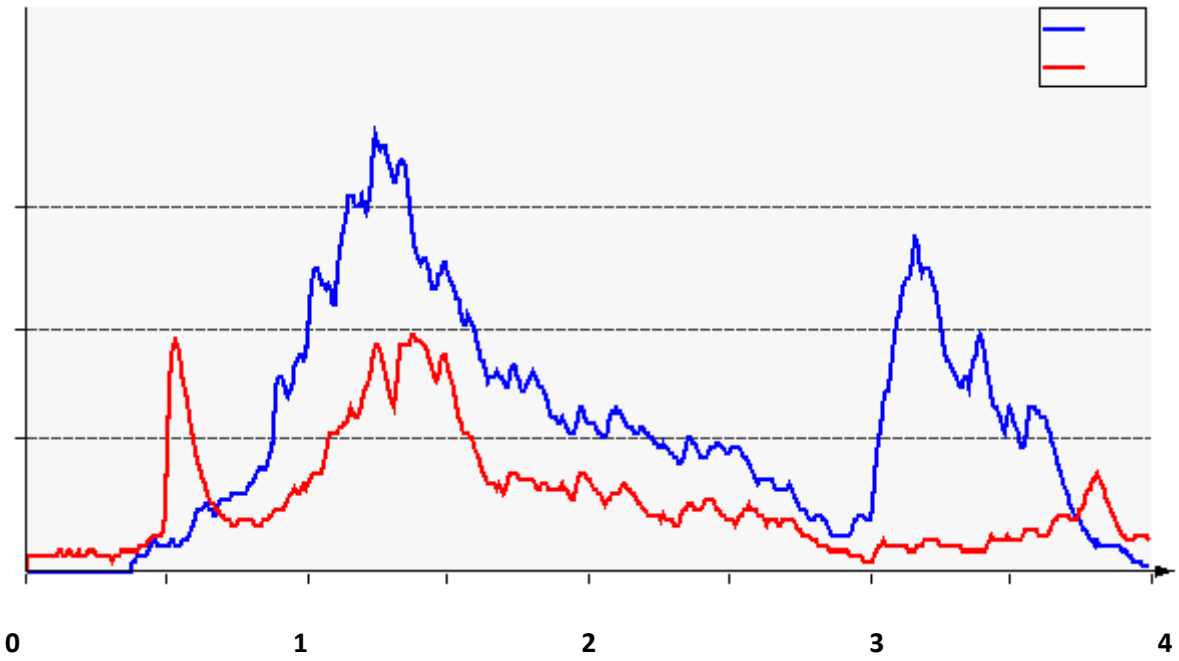

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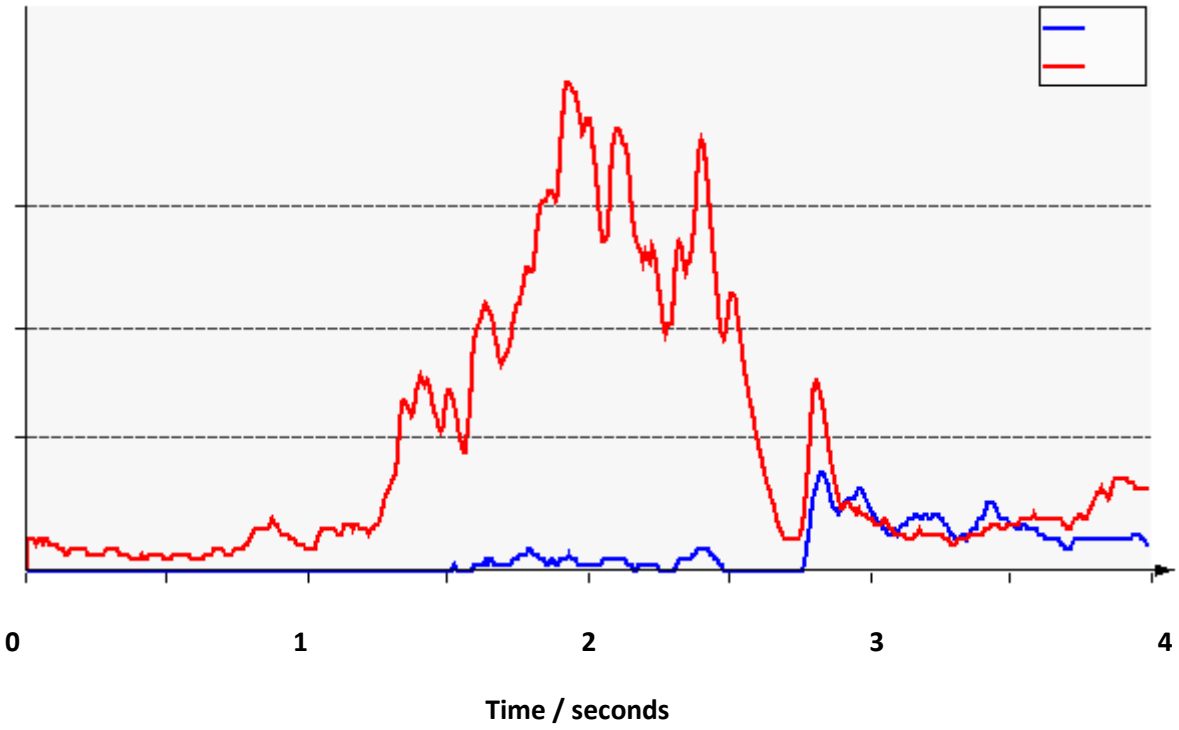
Hand to shoulder activity-1 Kg



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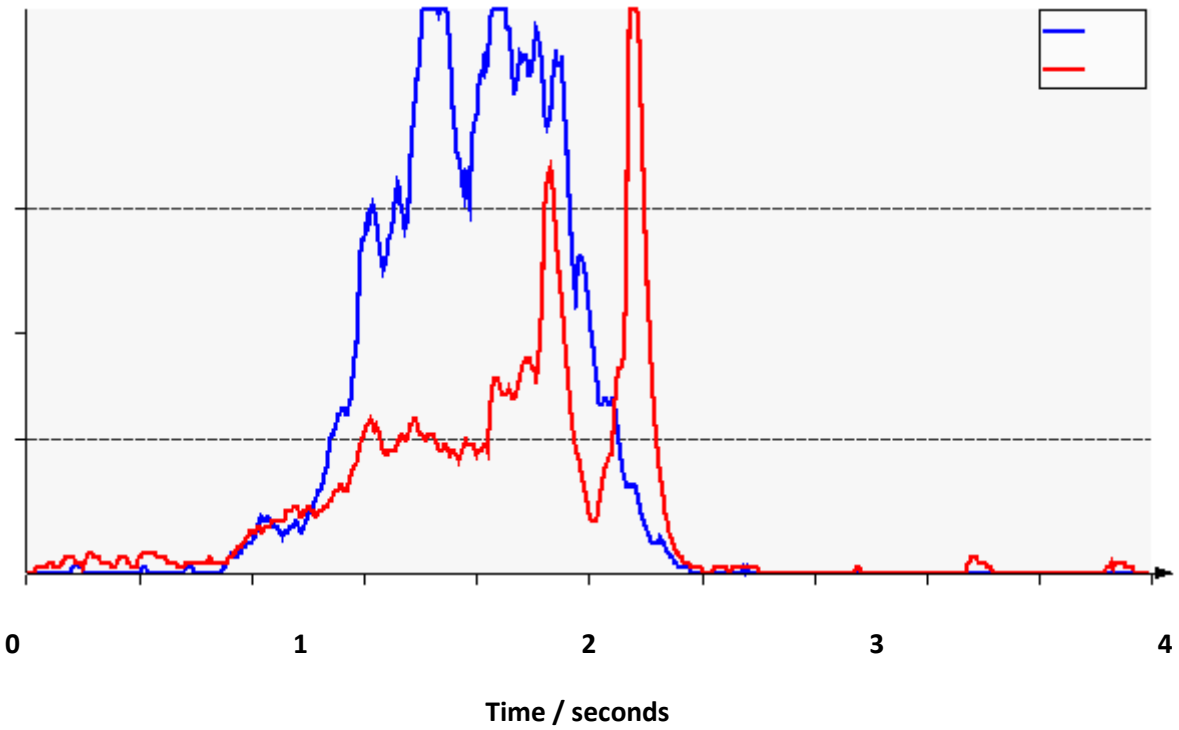

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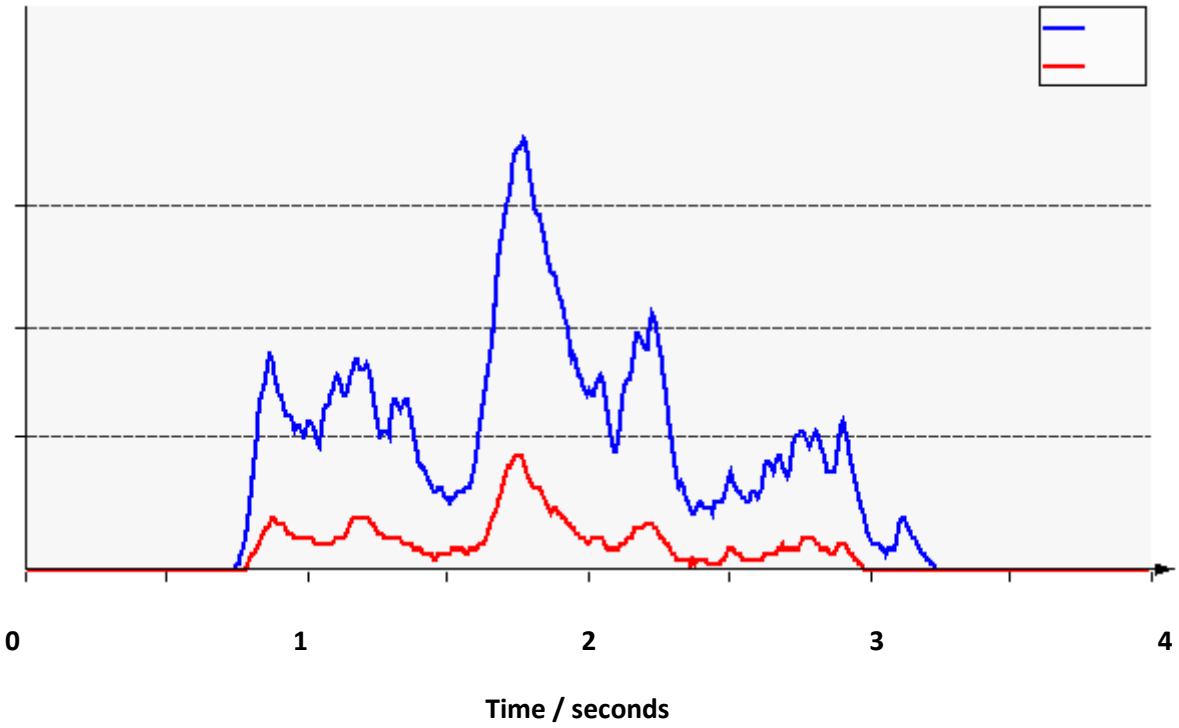

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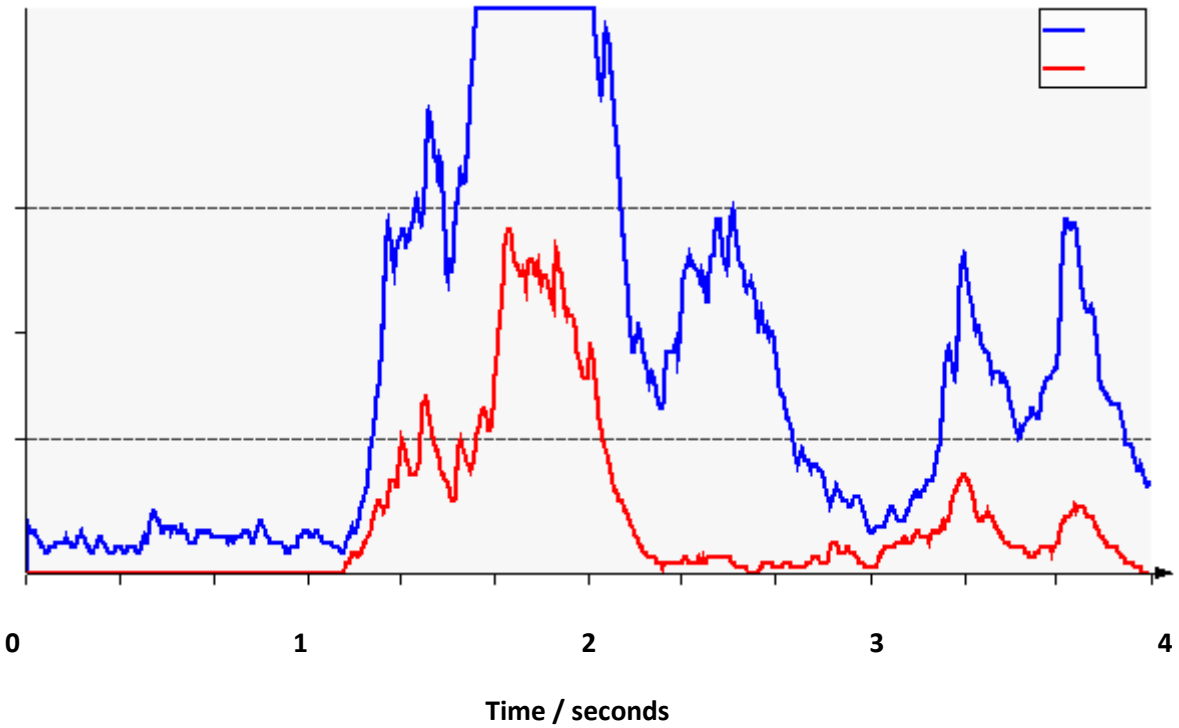
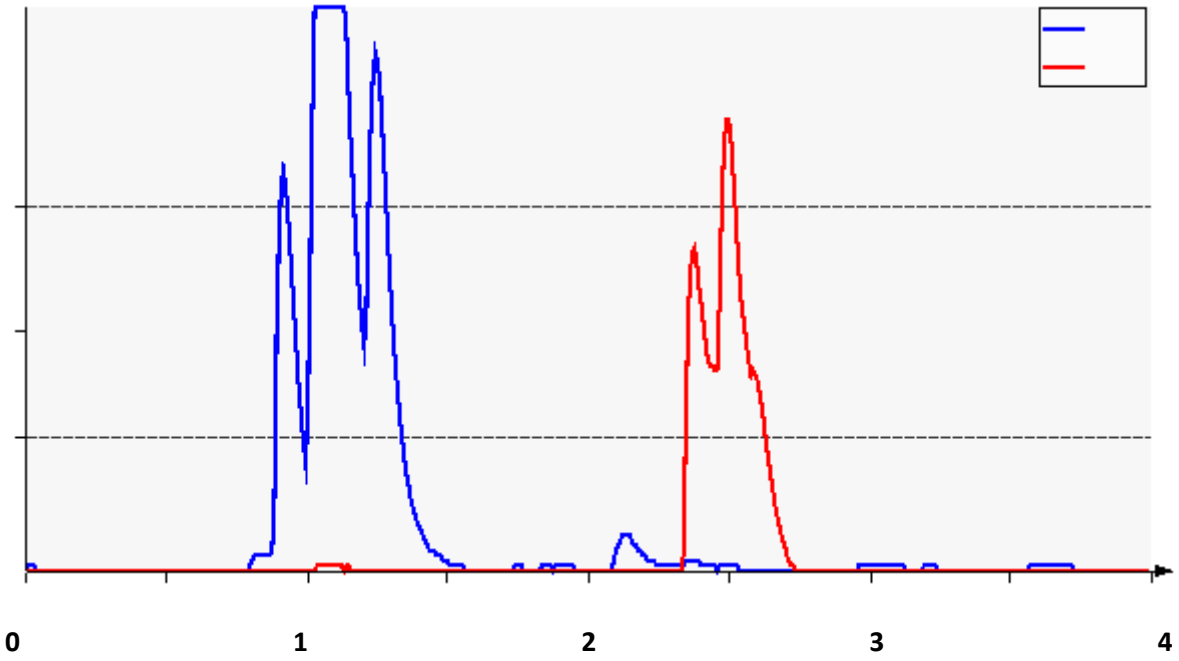


Subject E

Appendix D- *results of motion artifacts and movement analysis: signals acquired during the 'Hand to hip pocket' activity for each subject*

Hand to hip pocket activity-no load



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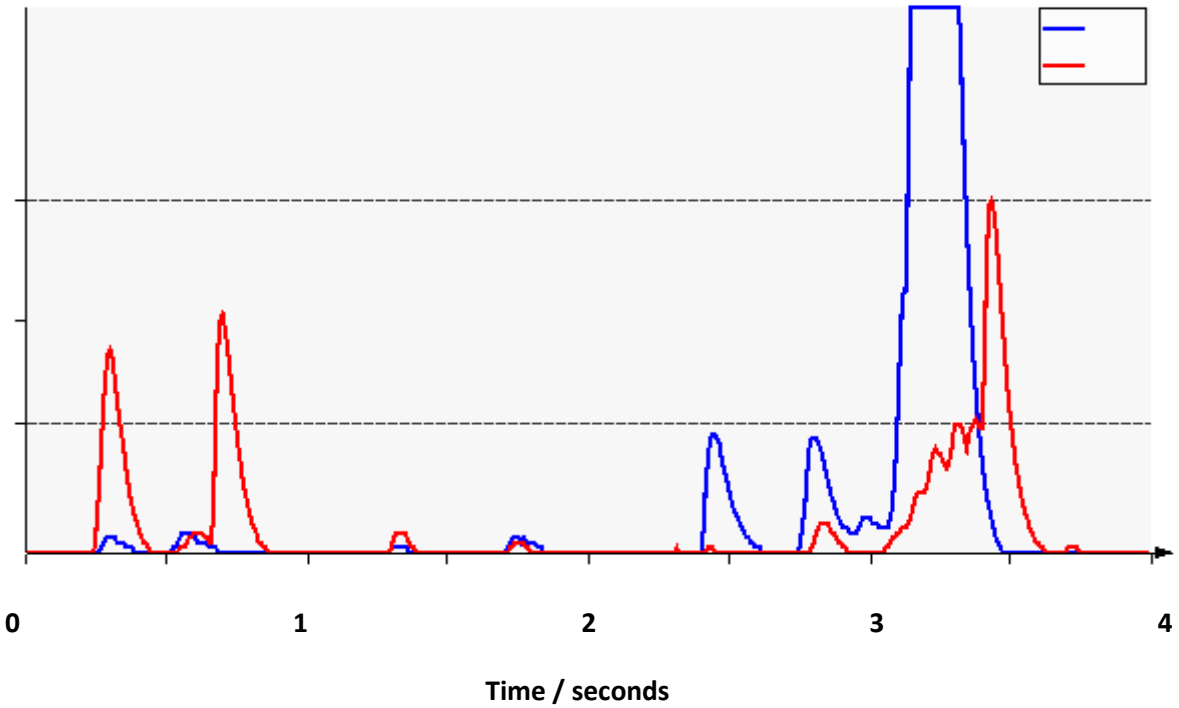

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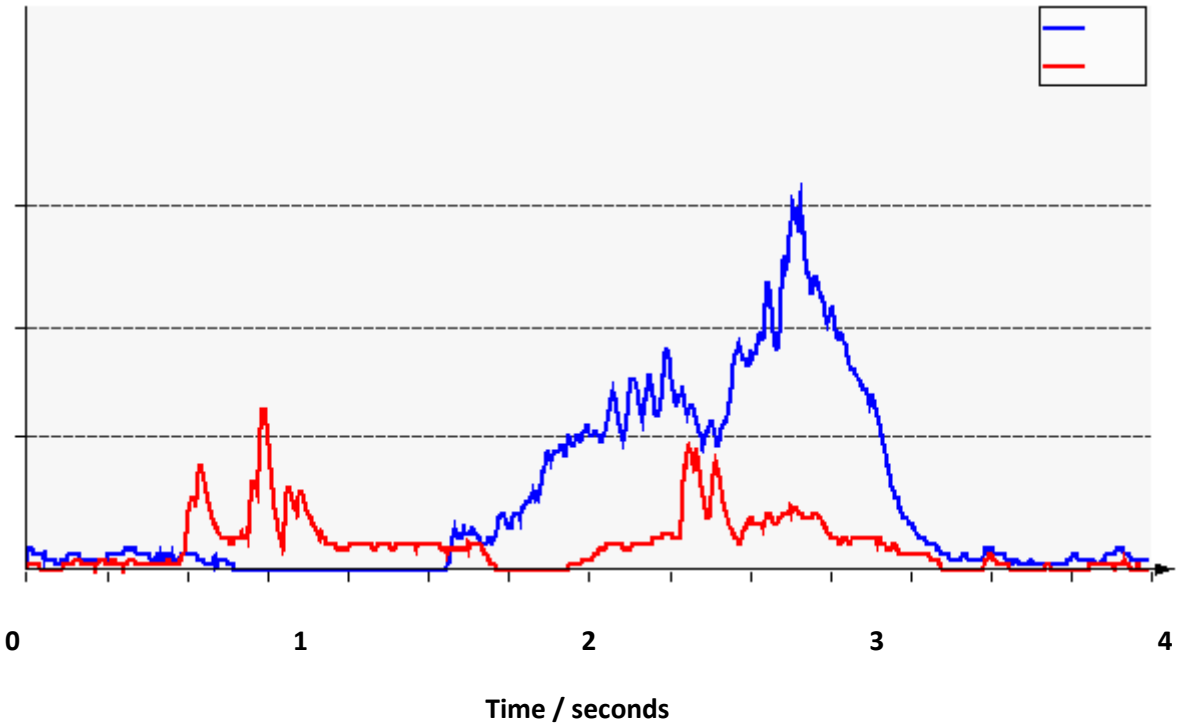

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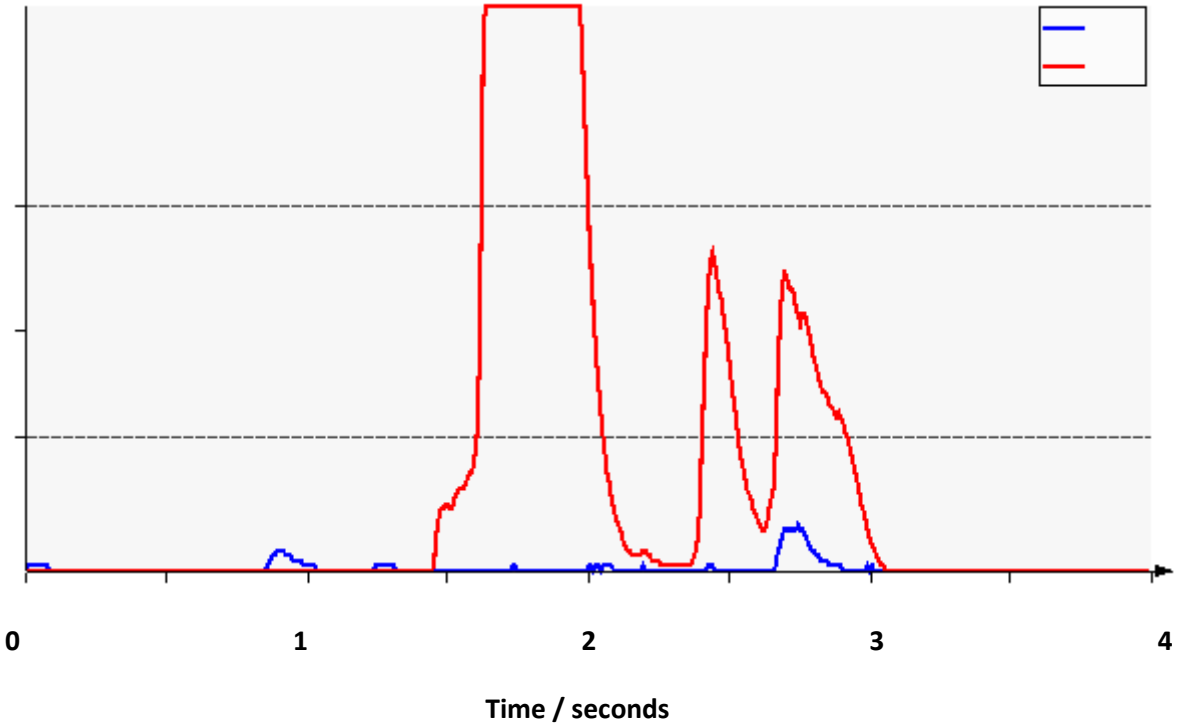
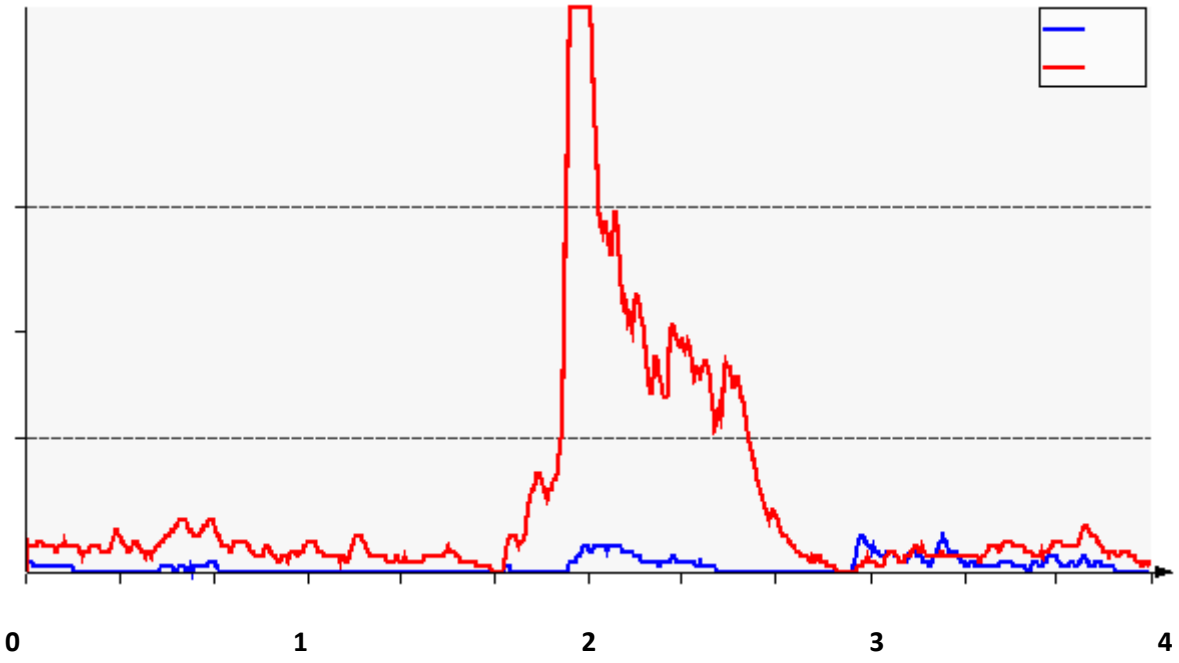


Subject E

Hand to hip pocket activity-500g



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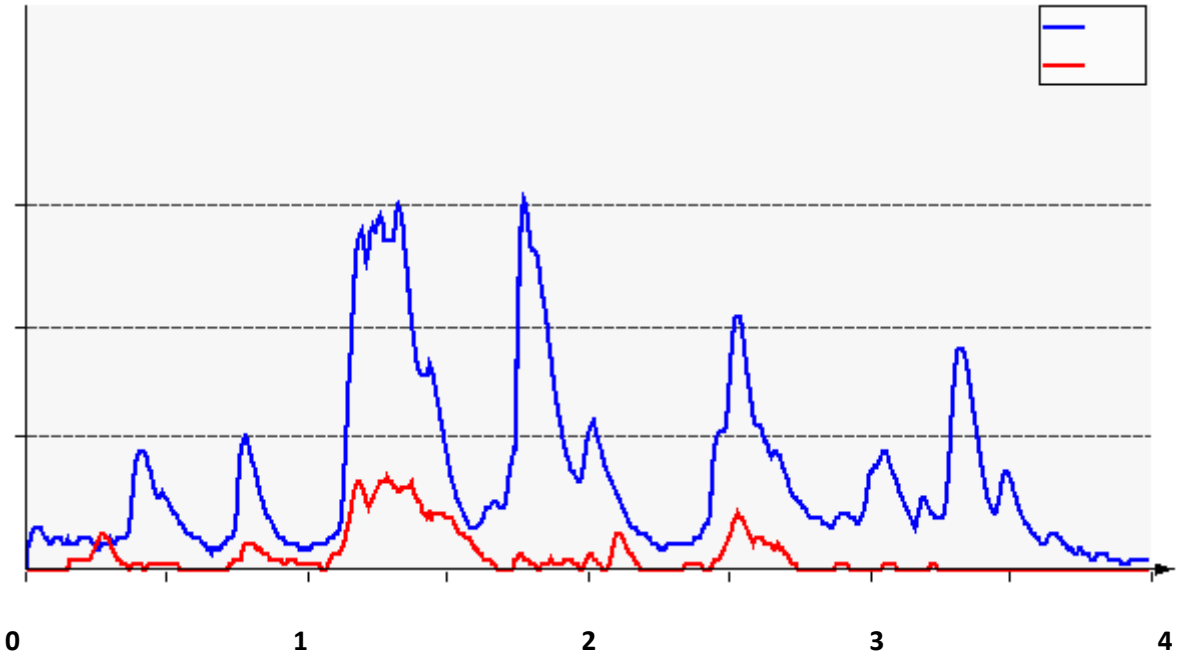

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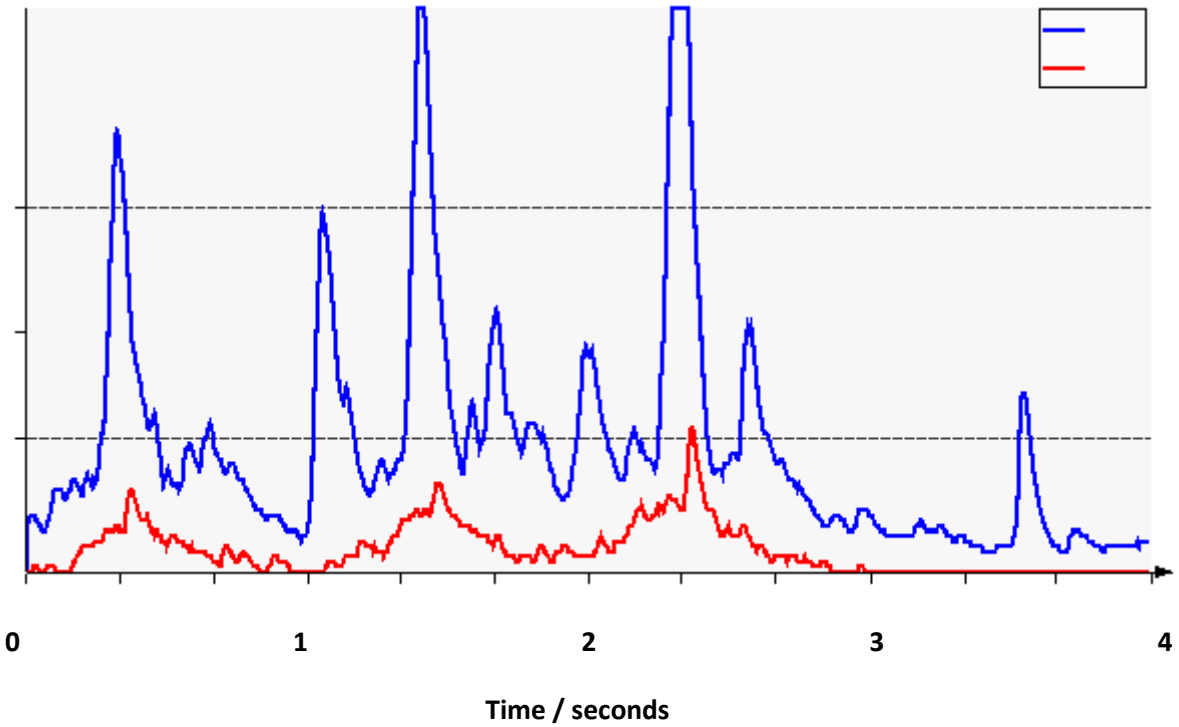

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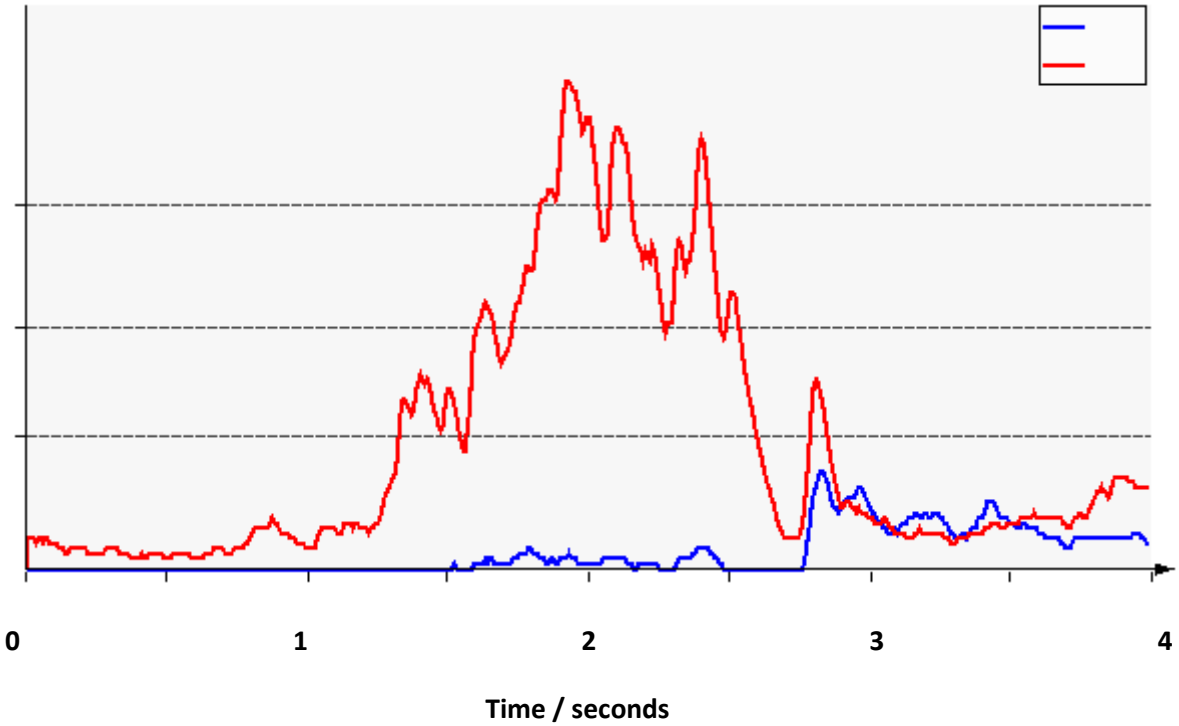

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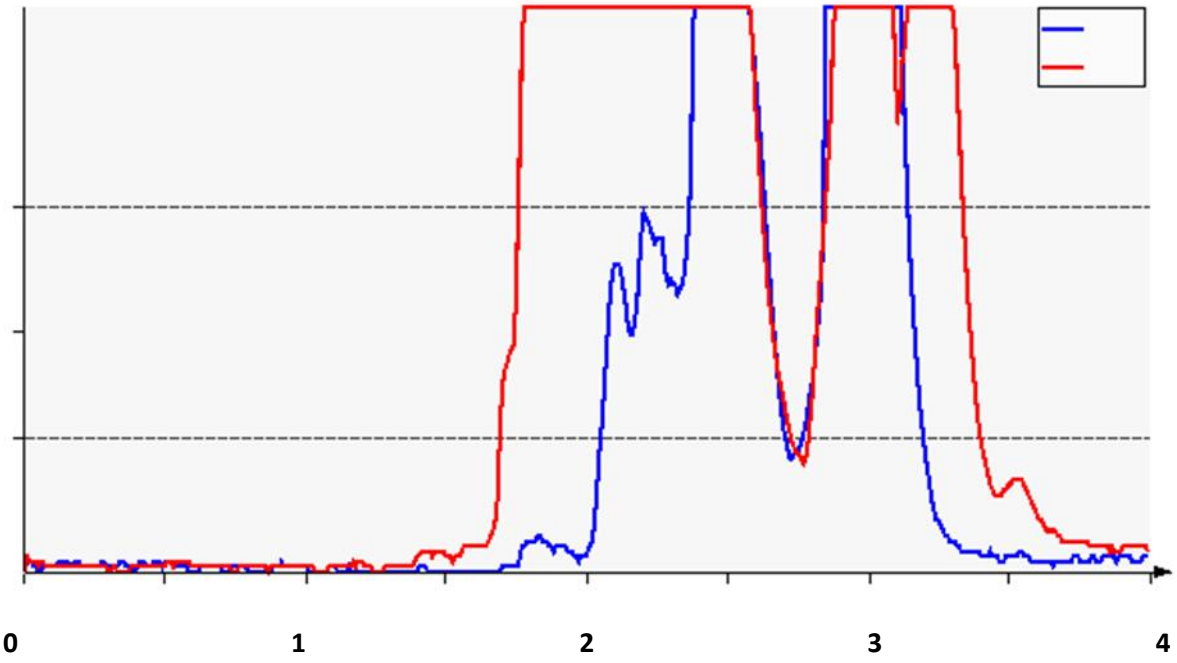
Hand to hip pocket activity-1 Kg



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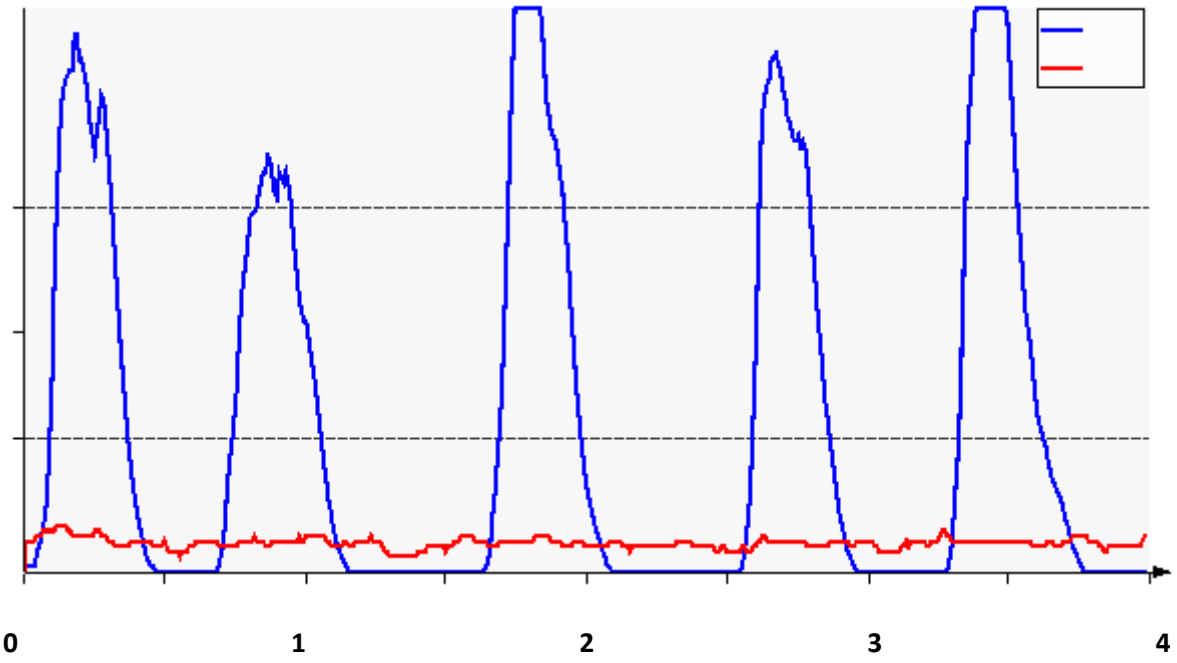

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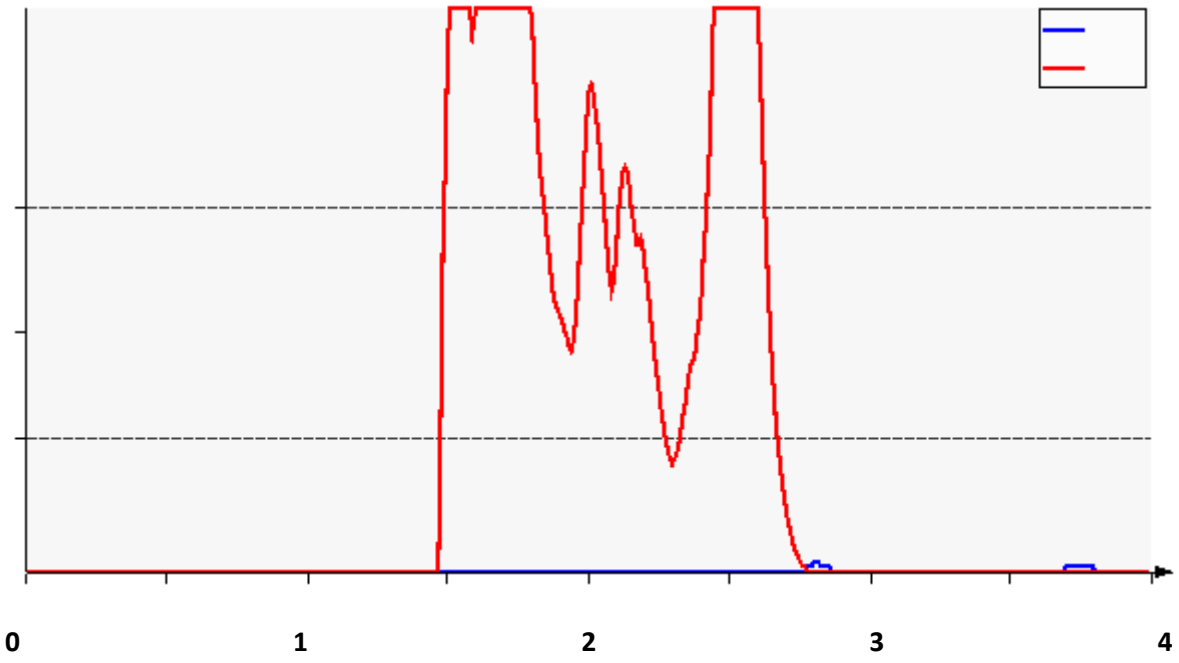

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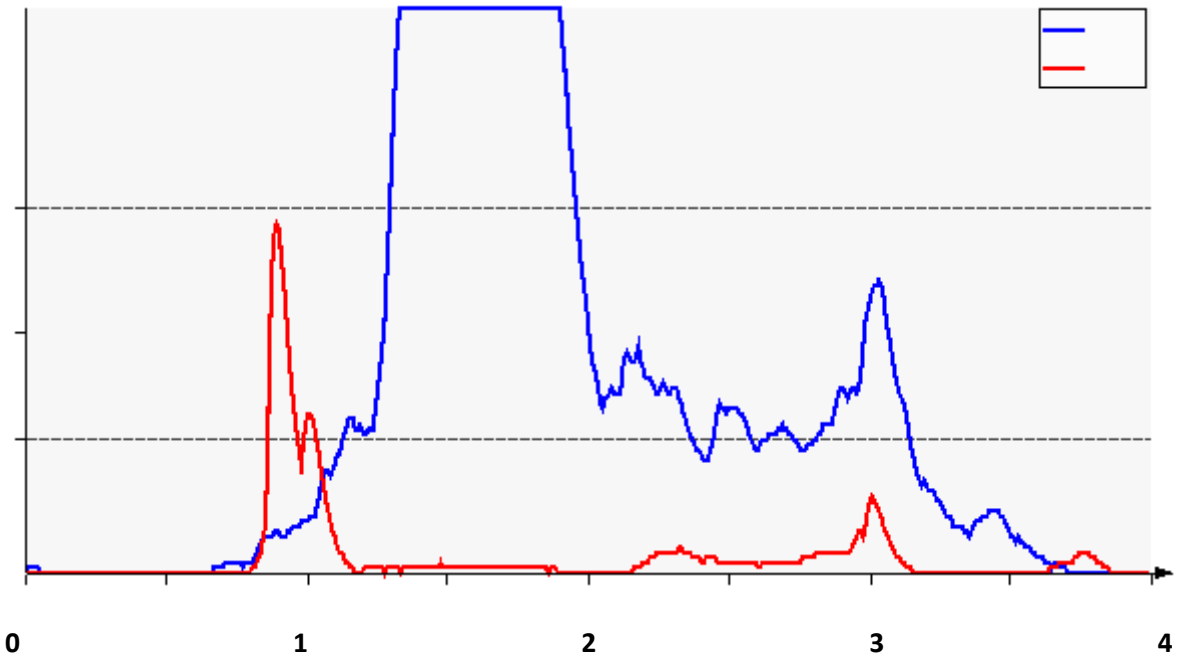

Subject E

Appendix E- *The changing education of Prosthetists*

The change in Prosthetic education and Upper limb Prosthetic education

The education of Upper limb Prosthetists within the United Kingdom has changed significantly since the late 1960's, the time period since the inception of myoelectric control (267). At this time, and for a period until the mid-1980's, Prosthetists were much more specialised in their clinical roles (130). For example, a Prosthetist would predominantly deal with service users at a certain level of limb absence; additionally, Upper limb Prosthetists would rarely, if ever, deal with lower limb prosthesis users. They would also become specialised in dealing with specific prosthetic cases or presentations; for example, an Upper limb Prosthetist may be specialised in Transhumeral prostheses for traumatic amputees.

The provision of a prosthetic service such as this, with large numbers of specialised staff, relies on certain key constants (268):

1. The retention of the staff at the service centre or disablement facility enabling the experience and skills to be developed by the Prosthetist for the relatively few prosthesis users at each level or treatment area
2. A long period of notice should the staff leave the facility which would enable the education and training of other Prosthetists within that treatment area or level of limb absence
3. A clear and healthy funding stream that enables suitably large numbers of staff to be available to meet the many specific areas of treatment and levels of limb absence

Above all, the constants highlighted above rely on a stable working environment with respect to the provision of prosthetic treatment. In addition, the training and education system employed for Prosthetists must be flexible enough to allow not only the basics of prosthetic treatment to be delivered but also the means of allowing specialist areas to be set up for individuals within the training programme (130).

Within this time period, the upper limb Prosthetist would normally be employed from within the existing working environment-for example, the individual sent for specific prosthetic training would previously be employed as a prosthetic technician (267). This had the advantage of the newly-qualified Prosthetist being:

a) Accustomed to the working environment

b) Familiar with the processes of the provision of prosthetic limbs and treatment

c) Most importantly, technically and practically proficient within what is ostensibly a 'hands-on' clinical role.

The disadvantages within this system however were numerous. The reliance on a stable working environment relied on a high level of staff satisfaction in conjunction with a system that was fairly static in terms of the labour market. In other words, individual clinicians would have neither have the need nor the desire to leave their positions for others within the sector. In addition, the academic requirements of the Prosthetists educational system would have to be geared towards those who were most likely to enter into it, e.g. technical staff. This inherently meant that the academic content was not of a sufficiently high standard to merit the award of an honours degree (267). Instead, the provision of British Technical and Education Council (BTEC) or National Diploma awards was offered for those entering onto the educational programme. Although this met the requirements of service users at a clinical and a technical level, it meant that qualified Prosthetists in the United Kingdom were not on a par academically with other clinical members of the rehabilitation team, such as Physiotherapists, Occupational therapists or Podiatrists, who often did not fully understand the professional role of the Prosthetist (269). It also inhibited the development of Prosthetic research activities at a postgraduate level, since Prosthetists themselves were not honours degree graduates and therefore did not follow the traditional route into research via an MSc or PhD (130).

It has been noted anecdotally, and referenced literature presented within this thesis also suggest this fact, that much of the prosthetic-related research undertaken and presented during the last few decades has originated from either Engineers (usually technically–orientated) or other rehabilitation therapists, e.g. Occupational therapists (usually clinically orientated). This thesis and the research conducted during its assimilation, has again highlighted this fact, since it is clear that the area of concern for the Prosthetist i.e. the upper limb socket, has received relatively little attention or improvement, whilst other areas such as prosthesis assessments (therapists) and myoelectric hands and systems (engineers) have been substantially reviewed and improved. Measures of clinical performance from Prosthetists have been rare, especially with regard to myoelectric prostheses. Additionally, the transition from technical opportunity to clinical availability, for example within myoelectric pattern

recognition systems and slip-sensor and thermal sensation technology, has been relatively slow. This transition process would naturally be undertaken by Prosthetists and the lack of research-led initiatives from Prosthetists has previously led to relatively slow improvements to clinically available prostheses, particularly those relating to the challenging area of upper limb replacement.

Initially, Prosthetists were trained in theoretical and related subject areas at Paddington College, in West London. Practical clinical education was obtained at the 'clinical placement centre' which was normally the technician's centre of employment, via an established 'Training Officer', who would be an experienced Prosthetist. The student Prosthetist would be introduced to the various clinical techniques whilst at the 'placement centre', which were delivered around the academic modules studied on the Paddington BTEC course.

The establishment of the specialised London school of Prosthetics educational facility for Prosthetists in England and Wales, associated with the disablement service centre at Queen Mary's University Hospital, Roehampton in 1984 bridged the gap between what had previously been a mostly-technical 'hands-on' educational format and a more formal academic approach. The London School prosthetics programme ran for 6 years, and focused very much on the most common clinical presentations and levels of limb absence (130). Theoretical principles of practice were also studied at a much greater depth than had previously been undertaken. The Paddington College programme was integrated within the London School programme in a sandwich type educational format (267). In addition, students on this programme were sponsored, and returned to clinical facilities when the School or College were out of term time sessions, thereby making the overall educational programme full-time. In total, this was a 4 year programme that incorporated a final year of study at a placement centre.

In the mid-1980's the situation regarding the training and education of Prosthetists in the United Kingdom significantly changed, particularly within Scotland following the Denny report in 1970, with the establishment of the National Centre for Training and Education of Prosthetists and Orthotists at Strathclyde University, Glasgow (130, 267). This centre established a 4 year undergraduate programme offering an honours degree dual qualification in Prosthetics and Orthotics. Previously, despite Prosthetists and Orthotists sharing

educational elements within their respective programmes, individuals could only qualify as *either* a Prosthetist *or* an Orthotist. The Strathclyde programme also incorporated a final year placement, split equally between Prosthetics and Orthotics.

In 1992, this revised degree-level educational format was introduced in England and Wales, via the 4 year Prosthetics and Orthotics educational programme at the University of Salford (267). Similar in structure and content to the programme in Scotland, this programme also consisted of a 3 year academic delivery on site within the University, followed by a clinical placement year, again split into two, 6-month placements, one in Prosthetics, and the other in Orthotics.

The amalgamation of training for Prosthetists and Orthotists, within a degree-type format, had a number of ramifications. Firstly, the professional status of the educational system and those that qualified from it was obviously enhanced. Secondly, the traditional route for research and postgraduate study could be realised for those graduates wishing to embark along this particular career pathway. Thirdly, and perhaps most importantly, the graduates would be introduced to a wide range of subject areas (269).

However, there were also some disadvantages with the degree-style format when compared to the previous educational system. The students would effectively be limited to term-time education only (they were not sponsored, but entered within the standard University UCAS format). This term time was extended somewhat on the P&O programme at Strathclyde University, but was still significantly less than the effective full-time education which was achieved in the previous diploma-led programme. The students entering the programme would not necessarily have previous practical and / or technical experience, particularly related to the specialised prosthetics clinical delivery. Instead, the entrance requirements would be much more academically focused, to reflect the increased academic status and theoretical content of the degree-level programme. This effectively meant that the practical skills required by the student for effective clinical work would have to be learned during the programme and beyond, and would challenge those individuals who though academically competent and therefore able to meet the programmes entrance requirements, were not as practically or technically gifted (269).

A third significant, potential disadvantage would be the time that could be spent on each professional discipline i.e. Prosthetics and Orthotics. Although closely related, these were still effectively two practising professions. Even now, despite the majority of clinicians within the United Kingdom being dual-qualified in both, anecdotal evidence suggests that the vast majority would appear to engage in clinical work in either, but not both, Prosthetics or Orthotics. The reduction in time spent on Prosthetic education was clear and this, in conjunction with a less technical and practical background, would significantly change the 'typical' Prosthetist in terms of their skills and experience (269).

In addition, the Prosthetist would be expected to deliver a clinical service to a wide range of prosthesis users, often across all levels of limb absence. Whereas previously, the upper limb Prosthetist would be clinically specialised, and would rarely if ever attend to lower limb prosthesis users, the new format of education would provide a more structured, more balanced educational system that enabled the graduate to effectively attend to the needs of many different types of service users. However, although this has the advantage of being more flexible with a more fluid system of clinical delivery, the acquisition of experience, and particularly that regarding the relatively rare sites of limb absence, such as upper limb prostheses, is much more restricted. This inevitably leads to modern Upper limb Prosthetists being much less experienced than their counterparts were in the past, and therefore puts more pressure on them delivering similar standards of prosthetic services without the requisite levels of clinical experience. In addition, the availability of improved, and expensive, myoelectric hands and other systems make the implementation of optimal electrode contact and socket fit within this area crucial for successful prosthesis user rehabilitation. Without the requisite availability of devices that enable the optimisation of signal acquisition, there is a clear danger that these improved technologies will not be utilised effectively. Anecdotal evidence from staff within the centres who assisted with the survey questionnaires within **chapter 3** suggests that these users were fitted with sockets that were made by experienced staff-even then; variances existed in terms of electrode and socket tightness and hand or prehensor response. It would be reasonable to suggest that more inexperienced Prosthetists would be less likely to produce an optimal fit, a fact also noted by numerous authors, and that these Prosthetists would therefore benefit by the provision of a device that enabled signal acquisition adjustments both at the prosthesis fitting stage and beyond.

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Publications associated with the thesis

Conference Presentations associated with the thesis

Head J, Heath GH, Hutchins S Kenney LPJ, Twiste M,. Analysing the relationship between electrode contacts and prosthesis functionality: a functionality assessment. Trent International Prosthetics Symposium, May 2009; Nottingham University campus, Nottingham, England.

Head J, Heath GH, Howard D, Hutchins S Kenney LPJ,. Analysing the relationship between electrode contacts and prosthesis functionality: a prosthesis user questionnaire. Trent International Prosthetics Symposium, May 2009; Nottingham University campus, Nottingham, England.

Head J. Advanced upper limb prostheses for sports amputees. English Institute of Sport medical conference, October 2011. Sports City complex, Manchester, England

Publications associated with this thesis

Head J, McLaughlin J, Kulkarni J, Heath GH, Hutchins S. Analysing the relationship between socket fit, electrode contact and myoelectric prosthesis usage and prehensor response: a prosthesis user questionnaire. Submitted to Prosthetics and Orthotics International, May 12th, 2013-paper under review.

Head J, Heath GH, Hutchins S, Kenney LPJ, Howard D. The use of an adjustable electrode housing unit to compare electrode alignment and contact interface security with myoelectric prosthesis functionality: a pilot study. Submitted to Prosthetics and Orthotics International, June 14th, 2013-paper under review.

The use of an adjustable electrode housing unit to compare electrode alignment and contact interface security with myoelectric prosthesis functionality – a pilot study

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separation between the electrode and the skin [1, 2, 3, 4]. Signal acquisition may also be inhibited if the electrodes are not placed in parallel to the line of action of targeted muscle fibres, which causes disruption to the clarity of the signal and could potentially cause a failure in initialising a response from the prehensor [5, 6]. In addition, maintaining the electrode in parallel to the muscle fibres has been shown to maximise the acquired signal strength, since the signal acquired will comprise of the summative voltage of all the fibres that are detected by the electrode[1, 5]. Misalignment of the electrodes can also increase the chance of cross-talk, where muscle fibres from muscles other than the target muscle may effect the signal acquisition of the electrode and hence the operation of the prehensor[6].

The electrodes used in most myoelectric prostheses are housed within the walls of the socket, and are fixed into position using semi-rigid locating rods. The housings themselves are created during the socket manufacturing process, and enable the electrodes to be conveniently inserted and removed. The outer surface of the electrode is exposed to the skin, allowing the Prosthetist to adjust the level of signal amplification and thereby to provide an appropriate signal voltage to operate the prosthetic device, which is normally a myoelectric hand.

However, finite changes to positions of the electrodes housed within myoelectric prostheses are not readily available in current designs, as there is little adjustment available which can be utilised to adjust the contact security or alignment of the electrode with respect to the skin once the electrode is fitted into its housing within the prosthetic socket. Although the concept of achieving a secure and intimate fit and correct electrode alignment between the electrode and the target muscles within the socket of a myoelectric prosthesis is generally regarded as essential for uninterrupted prosthesis usage and control[1, 2, 6] there is little evidence in the literature which has investigated the link between compromised electrode contact and electrode alignment on myoelectric prosthesis functionality.

Anecdotal evidence indicates that standard clinical practice is to follow the natural alignment of the residual limb and place the electrodes parallel to this alignment above the site of maximum signal strength, with the process being trial and error in some cases, particularly with regard to paediatric cases[7]. However, the remnants of the muscle tissue, and how it presents upon palpation of the residual limb, may differ between prosthesis users, particularly at the transradial level of limb absence which has multiple wrist flexors and extensors within the residuum[8]. Factors such as cause of limb absence, the nature of any traumatic injury plus any unique techniques employed during surgery will all contribute to differences in the layout of the muscle tissue and its alignment with respect to the residual limb[8, 9]. In addition, there are a number of different muscles that contribute to the overall muscle mass within a transradial residual limb, and these muscles will often cross over each other, making initial electrode position selection more difficult[1].

Providing an optimal electrode position on the positive plaster model is challenging, particularly for clinicians inexperienced in producing sockets for relatively uncommon myoelectric prostheses. Indeed, clinicians report that many myoelectric control problems emanate from a lack of electrode placement consistency over the appropriate sites[10, 11]. Myoelectric prosthesis rejection is commonly cited by users, with functional problems often quoted as a reason for lack of usage[12, 13, 14].

There was therefore a perceived need to develop a new design of adjustable electrode housing for use in upper limb myoelectric prosthetic sockets in order to potentially reduce prosthesis rejection rates by potentially improving functionality. To this end, this study examined the link between electrode and skin contact security and variations in electrode alignment with respect to resultant prosthesis functionality. This was achieved using myoelectric sockets adapted with a newly designed and novel contact-adjustable electrode housing device, which was able to offer three different alignment positions with respect to the

residual limb whilst attached to the socket. It also enabled the intimacy of contact between the electrode and the skin at both the negative and positive electrode contact points to be adjusted. The functionality available from the electrodes located within this housing unit was contrasted with the respective functionality available from electrodes located in standard housings. A validated, reliable functionality assessment procedure, the Southampton Hand Assessment Procedure (SHAP), was used to perform the functionality assessments [15].

Methods

Prior to the commencement of the study, ethical approval was received from the appropriate Xxxxxxxx Xxxxxxxxx Ethical Committee and the Xxxxxxxxxx xx Xxxxxxx Ethical Committee. Six transradial prosthesis users with experience of using myoelectric control were recruited for this study. Volunteer subjects were required to be experienced in using a myoelectric prosthesis, be aged over 18 with transradial limb absence from any relevant cause, and have acceptable cognitive ability to be included in the study. All volunteer subjects signed a consent form after reading a subject information sheet.

A standard transradial myoelectric socket was manufactured for each volunteer trans-radial prosthesis user. A bespoke endoskeletal prosthesis was also manufactured (**figure 1**) which allowed each socket for each patient to be interchanged and assessed with the same componentry. A plastic tubular unit was also sited within the distal aspect of the socket. This unit enabled the insertion of an aluminium tube, which in turn was connected to a screw-fastening wrist unit. An RSL Steeper 'MYA775' myoelectric hand was then attached to the wrist unit. The aluminium tubes were manufactured to suit the specific length needed in accordance with each subject's anthropometric measurements. Each myoelectric socket, for each separate subject, could therefore be fitted with the same components as their peers; thereby limiting the effects on the results of design factors not directly associated with the socket.

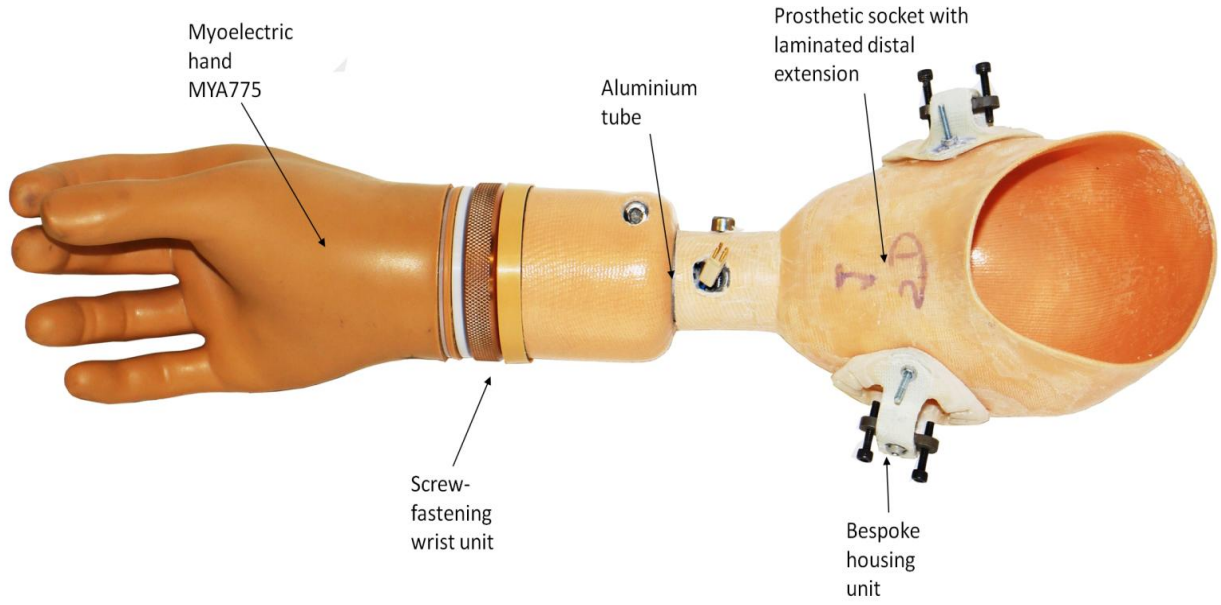

Figure 1: **An annotated illustration of the modular prosthesis used and the bespoke housing unit**

A series of novel, laminated electrode housings were produced specifically for the purposes of this study to be used to enable their effect on specific outcome measures to be compared to that of a standard housing unit.

The electrode used in this study was an RSL Steeper SEA200 standard clinical electrode, with semi-rigid locating rods, which is commonly used in clinical practice within the United Kingdom. This type of electrode is also identical in design format to others commonly used in the United Kingdom and elsewhere, such as the Otto Bock 13E200 and the 'i-limb' SPS800. A standard 2-site, 2-state threshold-controlled system was also employed, which used one electrode located over the remains of the wrist flexors to close the hand, and one electrode located over the wrist extensors to open the hand. The optimal electrode position for each subject was determined following a standard clinical assessment undertaken by an experienced Prosthetist, who located the position of the maximum myoelectric signal available from each muscle group. This therefore dictated the position of the standard electrode housing unit.

A bespoke housing unit was also designed to be attached to the same position to allow the electrode to be rotated about its central axis to provide different rotational electrode positions within the bespoke housing unit. A group of 26 inexperienced student Prosthetists were recruited onto the study and asked to position each electrode optimally. The two alternative electrode positions selected as the test position for this study represented the rotational position of maximum alignment variance from the optimum orientation previously determined by the experienced Prosthetist. These positions were measured using a hand-held goniometer and comprised of the angle measured between the upper edge of the electrode housing and a line drawn joining the medial or lateral epicondyle to the distal end of the ulna. Analysis of the results demonstrated that the maximal rotational positions away from that determined by the experienced Prosthetist were as follows:

- The alignment orientation was rotated by a maximum of 25 degrees, with the distal aspect of the electrode in a 'nose down' position with respect to the standard alignment position
- The alignment orientation was rotated by a maximum of 25 degrees, with the distal aspect of the electrode in a 'nose up' position with respect to the standard alignment position

These positions were measured by analysing the electrode alignment positions chosen by each student.

The electrodes were secured in each of these rotational positions for testing. The rotational position of these electrodes was measured using a goniometer. The bespoke electrode housing unit also incorporated 2 screw plungers, which could be used to adjust the contact security of each electrode across the surface of the skin. The screw plungers enabled the most intimate yet comfortable electrode contact perceived by the prosthesis user to be obtained (the users themselves were able to adjust the unit).

The same sockets were used for the assessments by designing the components so that the standard electrode housing and the bespoke housing unit described above could be interchanged to ensure any differences in functionality were due to alteration of the electrode housing design rather than other factors for each volunteer subject.

The functionality assessment had to be conducted using the standard electrode housings first, since these would have to be removed to allow for the fitting of the bespoke housing unit. However, each subject was provided with at least 20 minutes of practice prior to each assessment.

A functionality assessment for the bespoke prosthesis for each alignment position was then undertaken to determine if noticeable functionality variations could be linked to electrode rotational alignment. The functionality assessment used was the Southampton Hand

Assessment Procedure (SHAP)[15]. The SHAP was chosen because it is the only portable validated functionality procedure that has been specifically designed to accommodate prosthesis assessment, providing a quantifiable comparative score to that of a natural hand. The SHAP provides a functionality index score of between 0 and 100; 0 represents no hand function, whilst 100 represents that of a normal natural hand.

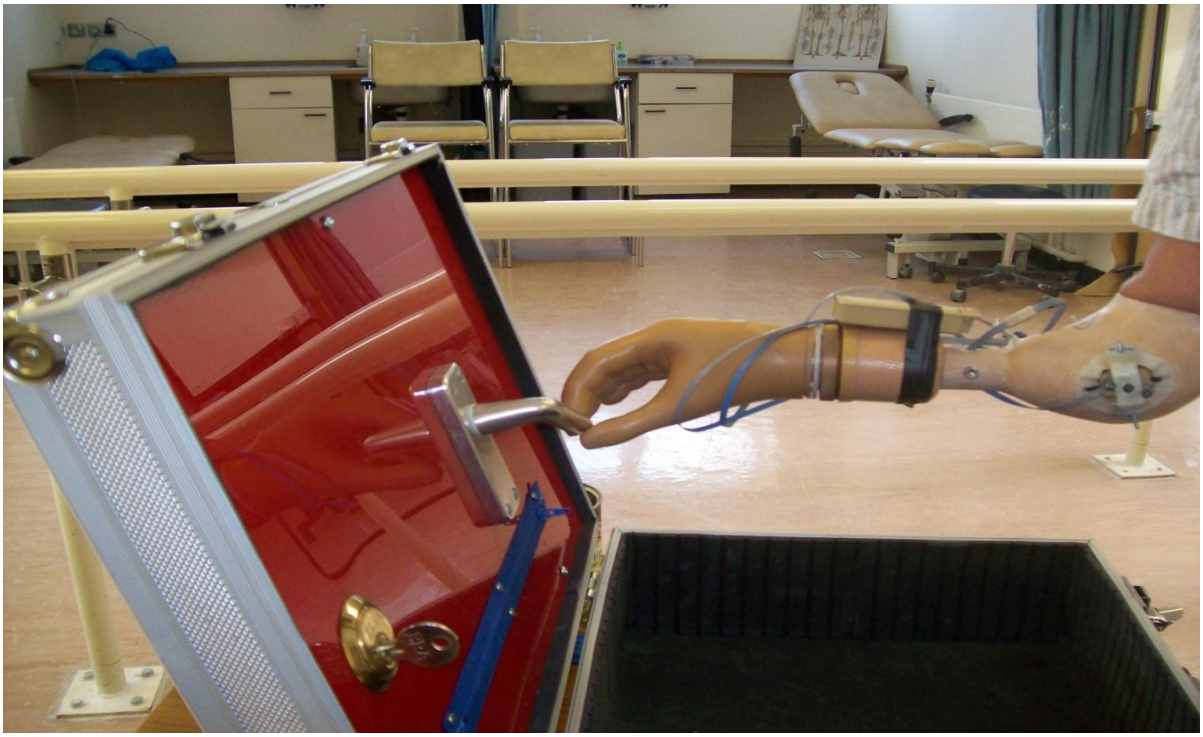

Figure 2: Subject 'B' undertaking part of the SHAP using the bespoke prosthesis and housing unit

Each subject was allowed to acclimatise to the bespoke prosthesis and the SHAP for at least 15 minutes prior to any assessment. During the main testing periods, three separate SHAP assessments were carried out for each electrode arrangement, by each subject.

The SHAP functionality scores were obtained for the following test conditions:

- A prosthetic socket with the standard electrode housing with the electrode positioned in the perceived optimal alignment via standard clinical assessment;
- The same socket with the bespoke electrode housing unit attached and with the electrode again in optimal alignment but adjusted using the plungers to improve the perceived contact security experienced between the skin and the electrode surface;
- The same socket with the bespoke electrode housing unit with the electrode rotated along its longitudinal axis by 25 degrees with the distal aspect of the electrode in a 'nose down' position with respect to the standard alignment position and again adjusted for perceived contact security;
- The same socket with the bespoke electrode housing unit with the electrode rotated along its longitudinal axis by 25 degrees with the distal aspect of the electrode in a 'nose up' position with respect to the standard alignment position and again adjusted for perceived contact security;

Each designated electrode position was identical for each electrode site, i.e. both electrodes were 25 degrees 'nose down' in this designated position.

A Kruksal-Wallis test was used to assess the significance of the data because it is a non-parametric analysis that is useful for small samples and independent variables, and was also employed for SHAP data analysis by Bouwsema et al (2011).[16]

Results

The mean SHAP functionality scores for each assessment using each test condition are represented below in **figure 3,** and **table 1**.

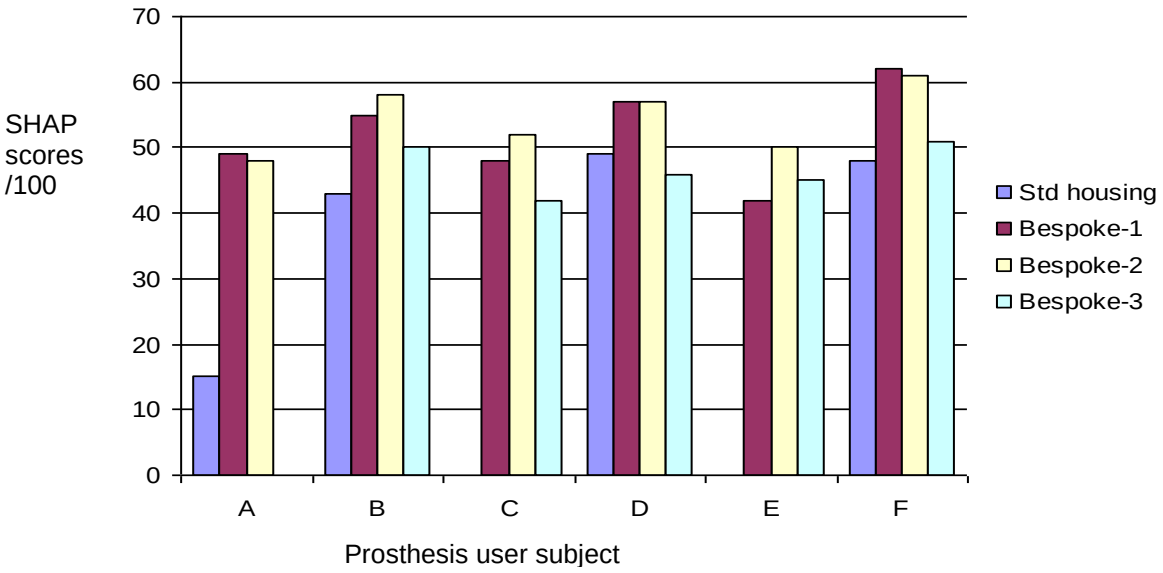

Figure 3: Mean functionality scores from each SHAP assessment with respective electrode alignment positions

- Std housing = Assessed optimal alignment, within standard housing
- Bespoke-1 = Assessed optimal alignment, within bespoke electrode housing unit
- Bespoke-2 = Alignment within bespoke electrode housing unit rotated 25^0 'nose down'
- Bespoke-3 = Alignment within bespoke electrode housing unit rotated 25^0 'nose up'

Test Condition	Mean SHAP Value (all tests)
Test 1: Standard opt. Align	25.83
Test 2: Bespoke opt. Align.	52.17
Test 3: Bespoke/ clockwise rotation	54.33
Test 4: Bespoke/ anticlockwise rotation	39.00

Table 1: Mean SHAP functionality index scores

The mean maximum SHAP score when using the bespoke housing (where contact security could be adjusted) compared to the standard housing was significantly increased in

all subjects by an average of 88%, where all scores were included. Where scores of 'zero' were excluded, this was still an increase of 32%. A Kruksal-Wallis independent samples test showed that for all subjects the SHAP functionality index scores achieved using across the standard housing (testing condition 1) was significantly lower than test conditions 2 & 3 at p=0.001, and significantly lower than test condition 4 at p=0.005. There was also a significant difference noted at p=0.025 between the test conditions 2 and 3 and test condition 4, although no significant difference between test conditions 2 and 3 was noted at p=0.025. The maximum average increase between the standard housing and the other test conditions was shown by user 'E', who had the shortest residual limb amongst the subject group.

The results (**figure 3**) showed clear variations between functionality when comparing the standard and bespoke housing units. For user subjects 'C' and 'E', the standard housing proved unusable. The use of this standard housing also resulted in a poor functionality score for user subject 'A'. Overall, the standard housing produced functionality scores which were the lowest recorded for 5 out of the 6 users. Employing an adjustable contact security device produced a clear and significant improvement in terms of prosthesis functionality.

Discussion

The standard electrode housings rely on the Prosthetist carefully contouring the appropriate electrode site area onto the positive plaster model. Although anecdotal evidence suggests that plastic or felt washers and/or elastic bands may subsequently be used on the outer surface of electrodes to enhance contact security in conjunction with standard housings, these do not provide the finite levels of contact control that are provided by the bespoke housing unit used in this study. Additionally, standard methods do little to ensure optimal contact across the surface of the electrode particularly if the electrode is able to pivot around the elastic band.

The variations also suggest that a housing arrangement that enables alteration to electrode alignment would benefit Prosthetists who are trying to achieve maximum signal acquisition for the prosthesis user. Although functionality score variations between the test conditions where the electrodes were rotated away from the optimal alignment position (i.e. test conditions 3 and 4) were smaller than those using the standard housing method (test condition 1), there were significant differences between the score for test condition 4 and the scores for test conditions 2 and 3 respectively. This is despite the fact that the electrode contact security could be adjusted using the bespoke housing mechanism in all these cases. For one subject, user 'A', electrodes in this position proved unusable.

Electrodes aligned in an anticlockwise position with respect to the standard position (i.e. with the distal aspect of the electrode rotated downwards) produced a significantly larger reduction in prosthesis functionality than electrodes aligned in the relative clockwise alignment position. It is therefore important to recognise these factors when determining electrode alignment, particularly as they can lead to a significant change in the resultant functionality of the prosthesis.

It is also worth noting that these alignment positions may be altered if the transfer of alignment marks from the original negative cast taken by the Prosthetist is not accurate, or if the dummy housing slips during the manufacturing process.

The lack of electrode adjustment in the myoelectric control system contrasts with the evident adjustability of other types of prosthesis control. For example, in lower limb prostheses, prosthesis control source is usually reliant on the biomechanical relationship between the body's weight line and the resultant ground reaction forces produced during the gait cycle. By providing optimum alignment between the prosthesis components, the Prosthetist is able to provide the platform for effective control for the prosthesis user. For this

reason, alignment devices and components within the prosthesis allow finite levels of adjustment, enabling optimal settings to be included prior to the delivery of the prosthesis, and at later dates should there be changes to the user's anatomy or requirements.

Conclusions

The use of an adjustable housing unit which provided the facility to provide alignment and contact security variations demonstrated significant variances in prosthesis functionality compared to the commonly accepted clinical standard. The number of alignment variations was limited to three in this study, and the unit itself was fixed which restricted the capacity of the system to provide more clinical fitting refinements. Nevertheless, despite these limitations, the unit was able to illustrate the changes in prospective functionality that may be recorded when even limited alignment alterations and contact security arrangement are provided.

As the clinical profile of the upper limb Prosthetist changes[17], with fewer specialist upper limb Prosthetists available to prosthesis users within the United Kingdom, and the capabilities of upper limb devices improve along with their costs, it is vital that every effort is made to ensure that requisite electrode contact and alignment adjustments are available. Providing optimal levels of electrode contact must be assured if the prosthesis user is to acquire the maximum functionality from their myoelectric prosthesis.

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Analysing the relationship between socket fit, electrode contact and myoelectric prosthesis usage and prehensor response: a prosthesis user questionnaire

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Abstract

Study design
This study investigated the effect of perceived socket tightness and electrode contact on prehensor response and myoelectric prosthesis usage patterns
Background
Optimum myoelectric control relies on secure and intimate contact at all times between the electrode, the socket and the residual limb. Failure to provide this could result in the development of motion artefacts, poor prehensor response and subsequent prosthesis non-usage.
Objectives
To determine the link between electrode and socket contact, prehensor control and overall usage patterns.
Methods
A validated questionnaire was distributed to myoelectric prosthesis users at Xxxxxxxxx, Xxxxxxxx xxxxxxx xxxxxx, Xxxxxxxxxx, Xxxxxxxxx.

Results
All users surveyed had disrupted prehensor response, ranging from 'rarely' to 'often'. Socket and electrode tightness was a factor in prehensor control and response, and significantly so with respect to electrode tightness and unwanted prehensor response. Lack of prehensor control did not appear to deter most users from wearing their myoelectric prosthesis frequently during the day.
Conclusions
Sockets which were not deemed a tight fit, but had secure electrode to skin contact, could potentially provide improved prosthesis prehensor response

Clinical relevance
Improving electrode to skin contact and providing systems that allow for this could assist prosthesis functionality, particularly in cases where tight fitting sockets are not always possible to achieve over a sustained period of time

Word Count: 2931

Background

Myoelectric prostheses use small ElectroMyoGraphic (EMG) signals generated from the contractions of residual limb muscles to operate electrically-powered components, usually hands. These signals are acquired via electrodes located within the prosthetic interface, (in this case the prosthetic socket), and may be used to control and operate electrically-powered terminal devices such as a hand, a wrist unit or an electrically-powered elbow.

Although myoelectric prostheses are the most modern types of upper limb prostheses, and offer cosmetic as well as functional appeal, their functional usage rates amongst prosthesis users appear to be disappointing[1-6.] Evidence suggests that some users still find body-powered prostheses more useful for some common tasks[7], although few surveys have been published dedicated specifically to myoelectric prosthesis usage; particularly those that investigate function.

The effective functionality of the myoelectric hand depends upon reliable, repeatable acquisition of the EMG signal, which in turn is reliant on a secure contact between the electrodes and the residual limb musculature[8-11]. If the electrode is able to either move with respect to the surface of the skin, or lift from this surface, then a 'false' myoelectric signal, called a motion artefact, may be produced[8-11]. If large enough, a motion artefact may cause unwanted myoelectric hand activation[10]. The loss of function associated with these artefacts would not only limit prehensor control but would negate the finite control needed for muscular co-contractions, which could otherwise be used to control other electrically-powered devices and improve overall prosthesis usability [12, 13].

This study investigated myoelectric prosthesis usage and reliability, with an emphasis on the relationship between socket and electrode contact security and myoelectric hand activation and response. Usage patterns were also compared with other prostheses, such as body-powered and cosmetic prostheses. Specific regard was afforded to the users' estimation of the fit of both the myoelectric socket and the electrode contact and its potential effect on the reliability or otherwise of the myoelectric hand. To this end, a questionnaire examining these factors was designed and distributed to myoelectric prosthesis users at Xxxxxxxxxx Xxxxxxxxx xxxxxx xxxxxx, Xxxxxxxxxx, xxxxxxxx Xxxxxxxxx.

The hypothesis was that a direct link would be demonstrated between the perceived tightness of the socket or the perceived intimacy of the electrode contact and increased control of the prosthetic hand for myoelectric devices.

Methods

The questionnaire was designed with the assistance of an experienced clinical multi-disciplinary team, including a Rehabilitation Consultant, Prosthetists, an Occupational Therapist, and academics specifically experienced in the design of healthcare-based questionnaires. Inclusion criteria included adult upper limb prosthesis users (aged 18 years and over) who currently used a myoelectric prosthesis. It was designed to be completed by myoelectric prosthesis users with any level of upper limb absence. Ethical approval was granted by xxx Xxxxxxxxx xx Xxxxxx Ethics Committee and also the local and national xxx ethics system (xxxx xxx xxxxx). Informed consent was obtained from each volunteer subject before being included in the study.

The questionnaire comprised of four sections, in a similar format to questionnaire-based studies by Pylatiuk et al (2007)[4] and Datta et al (2004)[2], with 3 sections focusing on personal/general prosthesis user information (Section A), the prosthesis activities undertaken (Section B) and the reasons for rejection of prostheses (Section D).

Questions from each section were broadly characterised as follows:

Section A:

- Gender / date of birth

- Date / Cause (if applicable) of limb absence
- Prosthesis usage rates (hours per day / days per week)

Section B:

- Prosthesis type / user rating for 1) functional use, 2) overall usability
- Length of prosthesis usage since first prescription
- Indoor activities undertaken using each type of prosthesis
- Outdoor activities undertaken with each type of prosthesis

Section D

- Time between prosthesis prescription and rejection
- Other functional prostheses still worn
- Factors relating to the reason for rejection

The fourth, unique section (**Section C**) to this questionnaire focused on the relationship between socket and electrode tightness and security and the associated response of the myoelectric hand. To rate the socket and electrode contact security, a likert rating scale was used, upon which the user could indicate their rating of both socket tightness and electrode tightness within their myoelectric prosthesis.

The user was asked to rate the tightness of both the electrode and the socket via the following questions:

1) Please rate the **general fit** of your myoelectric socket on the scale below, by placing a ring around the appropriate number: the ***lower*** the number, the ***looser*** the fit.

1 2 3 4 5 6 7 8 9 10

2) Please rate the fitting of the **electrodes** within your myoelectric socket on the scale below by placing a ring around the appropriate number: the ***lower*** the number, the ***looser*** the fit.

1 2 3 4 5 6 7 8 9 10

Likert scales have been used on numerous studies for this type of questionnaire, notably by Davidson (2004)[14] and Pylatiuk et al (2007)[4].

The user was then asked the following questions, relating to the responsiveness of their myoelectric hand:

2) ***Does the prehensor ever activate on its own when you don't want it to?***
3) ***Does the prehensor ever fail to activate when you want it to?***

The following options/answers were available to the prosthesis user for each of these questions:

- Never = (most reliable prehensor activation)
- Rarely
- Sometimes
- Often = (least reliable prehensor activation)

The user was again asked to ring the most appropriate answer in relation to their myoelectric hand and its responsiveness. These results were compared to information correlating the security or tightness of the prosthetic socket and the electrode contacts with resultant prehensor control reliability and the effect of this on prosthesis usage.

The questionnaire was distributed to all prosthesis users, at all levels of limb absence (n=40; over 18 years old) who had been prescribed a myoelectric prosthesis between the years 2000 and 2009 at Xxxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxx, xxxxxxxxx xxxxxxx, xxxxxxxxx. No specific cognitive tests were undertaken. Users were also asked about the usefulness of any other prostheses that were also supplied in addition to their myoelectric prosthesis, enabling a contrast to be made regarding the relative uses and usefulness of their myoelectric prostheses with these other prosthesis types.

Results

From the 40 questionnaires distributed, 12 were completed and returned (a 30% response rate). The response rate for this study was significantly lower than the 89% cited by Glyn and Hunter (1986)[15] and the 69% recorded by Kyberd et al (1998)[3]. A follow up investigation has been planned, as this has been shown to improve overall response rates[16].

The results are tabulated below in **Table 1** (General), and illustrated through **Figures 1a & 1b** (Activities undertaken with prostheses) and **Figures 2a-3b** (Relationship between socket and electrode contact tightness and prehensor response).

	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Level	TR	TR	TR	TR	TR	TR	TR	TR	TR	TR	TR	TR
Cause of limb absence	Tra.	Cong.	Cong.	Cong.	Tra.	Tra.	Cong.	Tra.	Cong.	Sarc.	Cong.	Cong.
Limb absence date	2005	n/a	n/a	n/a	1982	1985	n/a	1970	n/a	2007	n/a	n/a
Years since first myo prosthesis	1-5	10+	10+	10+	10+	10+	5-10	10+	10+	1-5	10+	10+
Still wearing myo prosthesis?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Duration of wear (days /week)	5	7	7	7	7	7	1-2	7	4	7	7	7
Hours / Day worn	4-5	16	10	12	14	8	4-5	14	7	14	15	16
Best for function?	BP	n/a	Myo	BP	n/a	BP	n/a	BP	Myo (only)	n/a	Myo (only)	Myo
Best prosthesis overall	None	n/a	Myo	Myo	Myo	Myo	n/a	Myo	Cos.	n/a	Myo	Myo

Key:
TR=Transradial
n/a = not applicable (the user did not have both functional types);
Sarc. = Sarcoma; Tra = Traumatic, Cong. = Congenital;
BP = Body-powered prosthesis; Myo = Myoelectric prosthesis; Cos. = Cosmetic prosthesis;
Y=Yes.

Table 1: Results of prosthesis functionality, cause of amputation and prosthesis type

The ages of the prosthesis users surveyed ranged from 23-68 years, with a mean age of 44.6 years, a slightly higher average age than most other similar surveys. All respondents were at the transradial level of limb absence, with males being the largest respondents by gender (75%). Those with a congenital limb absence accounted for 55% of the respondents, contrasting with other studies where trauma has been the predominant cause of limb absence.

Most respondents (67%) wore their myoelectric prosthesis for more than 10 hours a day; high usage rates in terms of hours were also noted in the mid-1980's by Millstein et al (1986)[17] and others have reported similar rates since then[1].

No respondents had abandoned their myoelectric prosthesis, even though 50% has also been supplied at some point with a Body-powered prosthesis, despite similar studies suggesting relatively high myoelectric prosthesis rejection rates. However, the generally low response rate must therefore be taken into consideration when reviewing general prosthesis wear. A follow up study is planned to acquire more information from those users or past users that did not respond to the initial questionnaire.

The myoelectric prosthesis was considered to offer the best overall features (i.e. cosmesis and function), by 58% of the prosthesis users who responded to this question. However, 4 out of the 6 of those users (67%) who had been prescribed a body-powered prosthesis stated that this provided better function than the myoelectric prosthesis, despite the fact that overall the usage rate of the myoelectric prosthesis was much greater than the body-powered prosthesis. This fact suggests that, for the prosthesis users surveyed here, the additional function provided by the body-powered prosthesis is outweighed by the additional cosmesis that is acquired from the myoelectric prosthesis.

The activities undertaken using each type of prostheses are illustrated below in **figure 12a** (indoor activities undertaken) and **figure 1b** (outdoor activities undertaken):

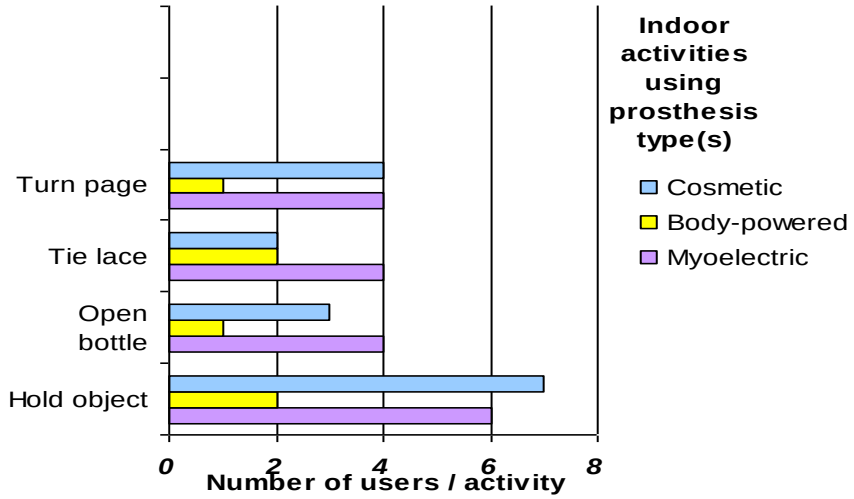

Fig 1a: Indoor activities undertaken using prosthesis/prostheses

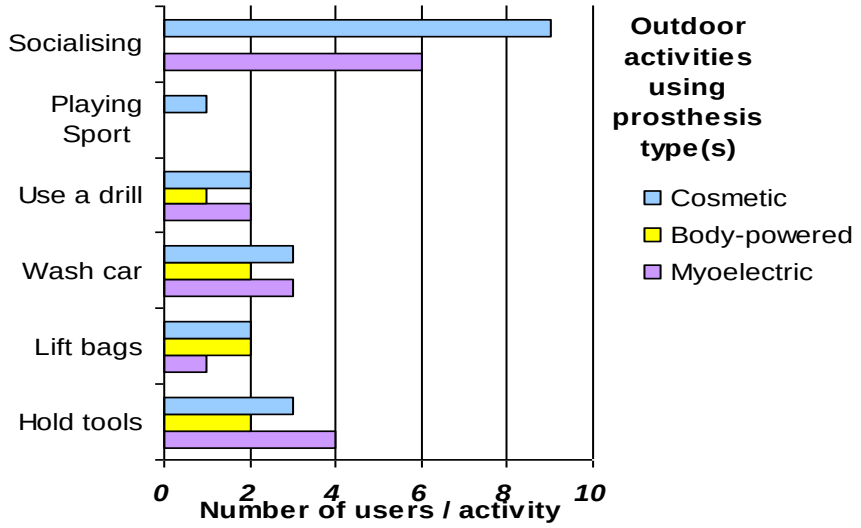

Fig 1b: Outdoor activities undertaken using prosthesis/prostheses

Social attitudes regarding cosmesis, and the decline of more traditional manual roles, may contribute to a change in emphasis with regard to prosthesis usage and wear[18]. This was reflected in the fact that none of the prosthesis users wore their body-powered prosthesis when socialising, whereas this was the most popular use for cosmetic prostheses and myoelectric prostheses.

Cosmetic prostheses and myoelectric prostheses appear to offer almost symmetrical patterns with regard to overall usage (f**igs. 1a & 1b**). The results demonstrate that body-powered prostheses are used generally more infrequently, although it should be remembered that only 30% of the users surveyed had access to a body-powered prosthesis. Taking this figure into account, it is clear that for those users that have access to them, body-powered prostheses are used for many functional tasks, particularly those outdoors (f**ig. 1b**). The similar patterns of usage for cosmetic and myoelectric prostheses suggest that cosmetic prostheses are also able to provide reasonable levels of function, as documented by Fraser (1992)[19].

<u>Section C:</u> Results related to socket and electrode fit and prosthesis response

Part 1: Response to the question**: *"Does the prehensor / hand ever fail to activate when you want it to?",*** matched against user's ratings for: 1) socket tightness and 2) electrode tightness.

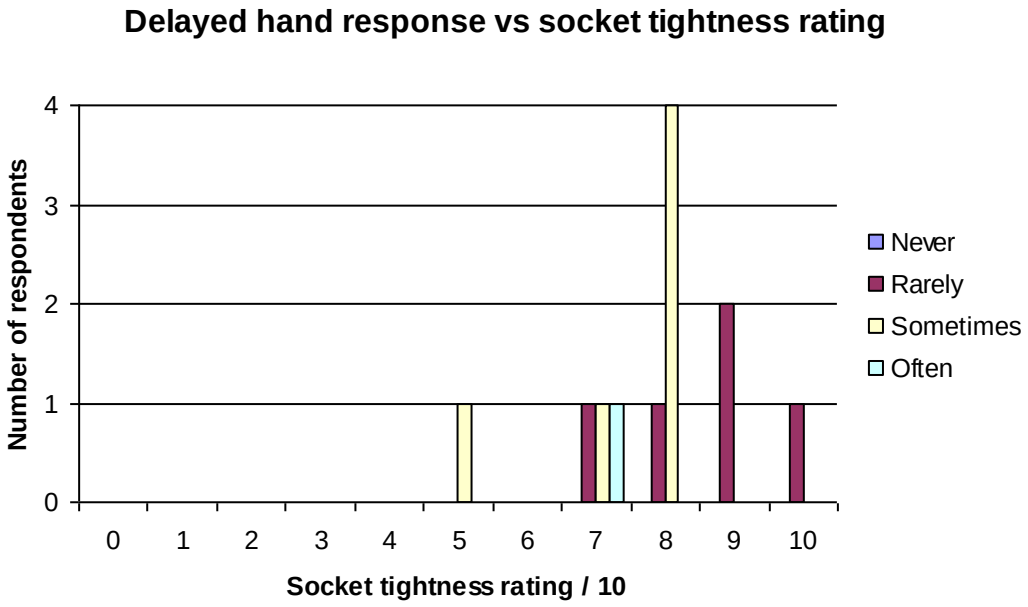

Fig 2a: Delayed myoelectric hand response vs socket tightness rating

The unique requirements of the prosthesis user, together with variations in the presentation of the residual limb, mean that socket fit can vary, and this appears to be borne out by the variation in socket fit inherent in the results (f**igs 2a & 3a),** although the rating is still relatively subjective.

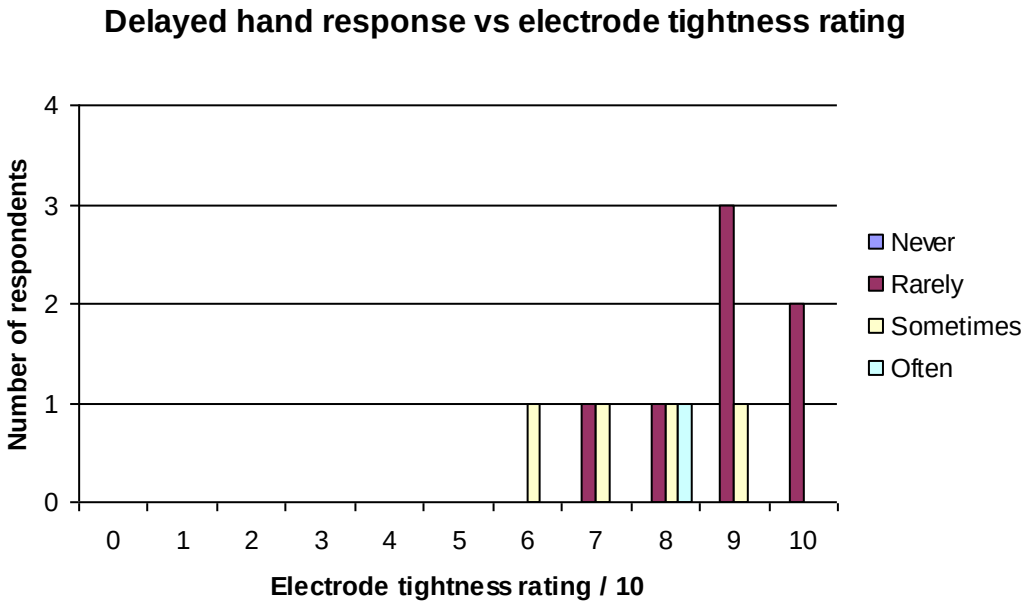

Fig 2b: Delayed myoelectric hand response vs electrode tightness rating

Part 2: Response to the question**: *"Does the prehensor / hand ever activate on its own when you don't want it to?",*** matched against user's ratings for: 1) socket tightness and 2) electrode tightness

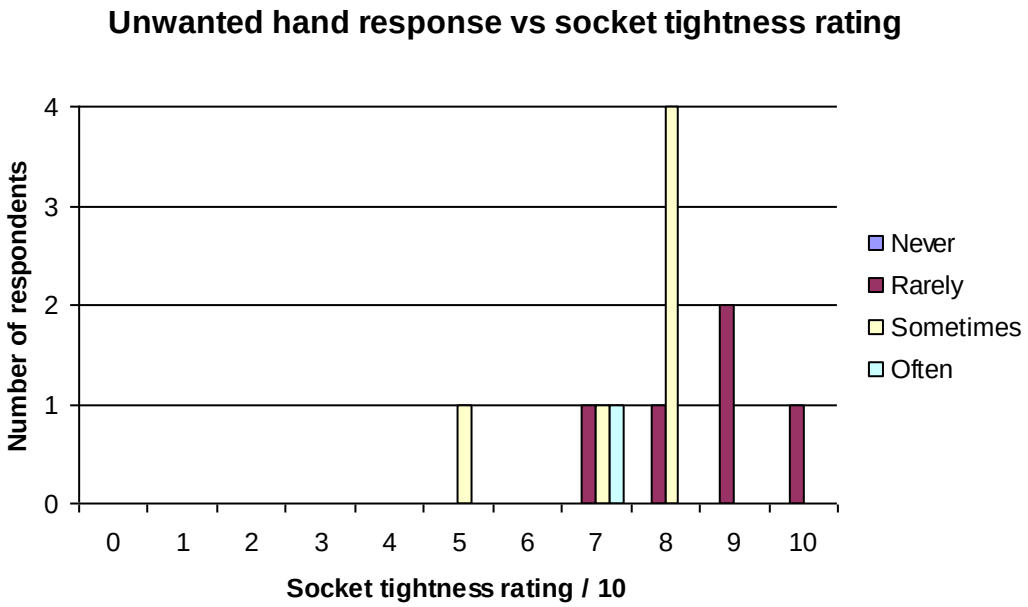

Fig 3a: Unwanted myoelectric hand response vs socket tightness rating

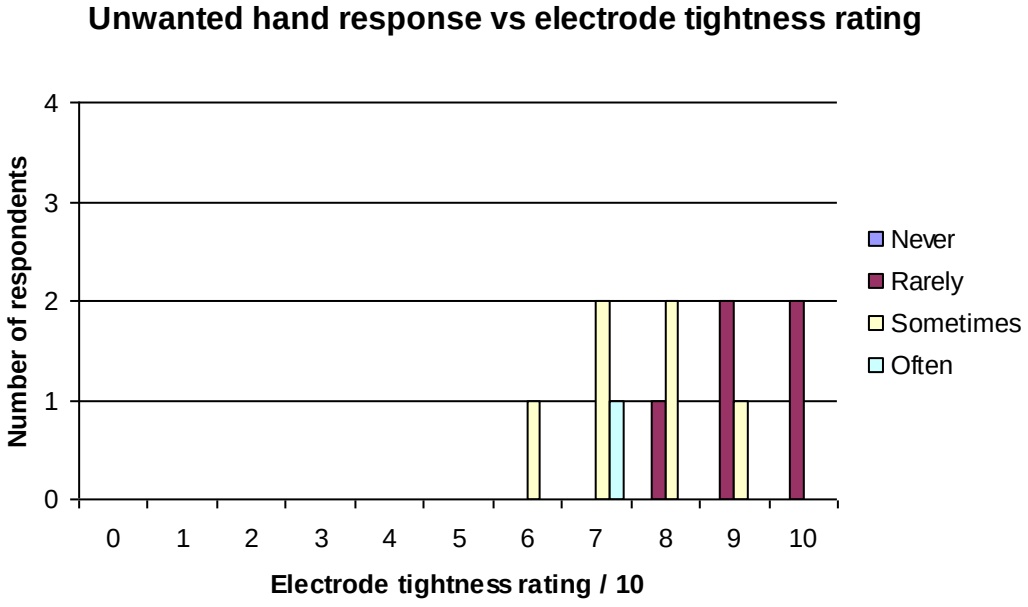

Fig 3b: Unwanted myoelectric hand response vs electrode fit

Section D: *No users rejected their myoelectric prostheses*

Figures 1a-3b demonstrate that more reliable prehensor operation is achieved using a secure socket interface and stable electrode contacts, a fact also noted by Daly (2000)[20]. However,

this apparent trend was not found to be statistically significant, using a Mann-Whitney test, at p=0.05, for a lack of prehensor response linked to either socket or electrode tightness (**figs 2a & 2b**). Where unwanted prehensor response is concerned (**figs 3a & 3b**) statistical significance ***is only attained for an improvement in unwanted response with a tighter electrode contact***, not for socket fit, at again p=0.05.

Discussion

Clinicians agree that achieving an optimum socket fit is the most important factor for successful prosthesis usage. However, the definition of 'optimum' is often subjective, with many prosthesis users favouring socket fits that are clearly different to the prescribed 'norm'. In myoelectric prostheses, a tight socket would appear to be an obvious requirement; since the electrodes that rely on an intimate fit at all times with the residual limb are housed within the socket walls. Consequently, a tight socket should restrict any movement between the electrodes and the residual limb thereby reducing motion artefacts. However, common socket designs used for myoelectric prostheses are often simple variations of those used for other types of prostheses, e.g. cosmetic prostheses, which do not normally require such an intimate fit. As a result, a tight fit is not always easy to establish, and even when it is achieved, this may not satisfy the prosthesis user in terms of comfort.

The results suggest that a tight socket does not necessarily guarantee a secure contact between the electrodes and the skin of the residuum. Furthermore, as well as overall security, the electrode should have equal pressure maintained over its entire length if disturbance-free operation is to be achieved[8]. These results could also be linked to the condition of the myoelectric system and the course of repair and refurbishment administered. Anecdotal evidence suggests that some prosthesis users attend clinics more frequently then others and a poorly maintained myoelectric system will not provide optimum control.

Methods for enhancing electrode contacts between the residuum and the electrode have included the use of roll-on silicone sockets, specifically designed to increase socket suspension and lack of motion, which have generally improved signal uptake and prosthesis control[20, 21]. Nevertheless, difficulties remain for upper limb prosthesis users with regard to donning roll-on sockets, and problems with perspiration and skin care are also factors in their usage and general uptake. Detachment of the electrode from the skin will lead to motion artefacts and unwanted activation of the prehensor, as well as failing to provide a basis for myoelectric signal transmission. The results from this study suggest that unwanted prehensor activation and a failure to activate the prehensor when required are both affected by socket and electrode variations with regard to the tightness of fitting, although alteration to electrode tightness is more significant in reducing this phenomenon.

Socket volume matching and residual limb growth also provide challenges with respect to paediatric socket fitting. Children are often prescribed myoelectric prostheses, primarily because they are inherently quick at learning new techniques, and because of the cosmetic and technological appeal that myoelectric prostheses offer both them and their parents[22]. However, continual residual limb growth during childhood will effect the provision of a continually optimum socket fit[23, 24, 25], thus potentially limiting the effectiveness of the myoelectric system. A localised system of adjustment for the electrode housings and contacts may be more practical for signal acquisition than numerous remakes of the prosthetic socket.

The consistently high usage rates exhibited by prosthesis users involved in this study suggests that myoelectric prostheses are worn as much for their cosmesis as for their

functional value. The intermittent functional response illustrated by some of the myoelectric prostheses appears to have little effect on their daily usage. As with all prostheses, upper limb prostheses must offer a higher benefit versus cost ratio for the prosthesis user. In other words, the prosthesis user must see an overall benefit in terms of the factors as stated, such as function, cosmesis and comfort. It may be that this benefit ratio is still satisfactory, even with a relatively ineffective or intermittent functional response. However, this should not preclude the adaptation and functional improvement of current myoelectric prostheses.

Conclusions

An intimate socket fit is important in virtually all prostheses, and myoelectric prostheses are in principal no exception to this rule. However, residual limb volume changes over time and immediate changes in shape under muscular contraction within a rigid socket make maintaining secure electrode to skin contact particularly difficult. Placing the electrodes on the residual limb in the optimum position, and achieving a signal of usable strength, is a challenge for Prosthetists. The electrode location is very much 'trial and error' in some cases, particularly if the Prosthetist is inexperienced with regard to myoelectric prostheses fitting.[25]

This survey has shown that close fitting sockets and close fitting electrode contacts are not always intrinsically linked. Electrode contact with regard to unwanted prehensor response is the only factor that has a statistically significant effect on prehensor control and activation and interestingly only with regard to unwanted activation. Therefore, it may be possible to derive an electrode housing that could singularly resolve the myoelectric contact requirements by offering the facility of the user to be able adjust the intimacy of electrode to skin contact themselves whilst the prosthesis is being worn.

The authors would recommend that further studies of this type are performed, using greater numbers of prosthesis users and over a longer period of time, to explore myoelectric prosthesis wear and the long-term factors that affect myoelectric prosthesis usage.

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